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FDA - Blood Glucose Meters Meeting 03-17-2010

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FDA PUBLIC MEETING
CLINICAL ACCURACY REQUIREMENTS FOR
POINT OF CARE BLOOD GLUCOSE METERS
March 17, 2010

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1 P R O C E E D I N G S

2 DR. HARPER: If everyone could please take
3 your seats, we'd like to get started. So welcome back
4 to all of you who joined us yesterday for the first
5 day of FDA's public meeting on blood glucose meters.
6 Hopefully you've had a chance to think about what was
7 discussed yesterday and come back for more discussion
8 today on anything you might have thought of or some
9 questions you didn't get to ask. Today, we're really
10 looking forward to having additional discussion on
11 liability, tight glyceimic control in hospitals, human
12 factors and use of glucose meters by patients, and use
13 of in hospitals at point of care and risk mitigation
14 issues.

15 So first of all we'd like to start with a
16 very exciting talk by Jack Bierig. Jack Bierig has
17 extensive experience in litigation challenging
18 government action affecting healthcare providers,
19 copyright and trademark cases and FDA matters. He
20 counsels clients on a wide variety of antitrust
21 association law and regulatory issues. He represents,
22 among others, the American Medical Association and the

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1 College of American Pathologists. He will be talking
2 today on liability issues and the use of blood glucose
3 meters. So I'll welcome Jack Bierig. Thank you.

4 MR. BIERIG: Thank you, Courtney. I'm
5 honored to be exploring with you this morning on this
6 St. Patrick's morning the issue of malpractice for
7 hospitals and healthcare practitioners in the use of
8 blood glucose meters. I should disclose at the outset
9 that my law firm, Sidley Austin, LLP, represents a
10 number of manufacturers of these meters, although I
11 myself have never worked for any of those companies.

12 I'd like to begin by encapsulating in a
13 single sentence a general statement of malpractice
14 law. There is malpractice liability if three
15 conditions are met. The hospital or practitioner owes
16 a duty to the patient that was negligent in the
17 performance of that duty, and that negligence was the
18 proximate cause of the injury to or death of the
19 patient. Here, the first and third condition are
20 quite straightforward. Hospitals and practitioners
21 have a duty to patients to provide proper equipment
22 and to utilize such equipment properly. Likewise, it

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1 is quite foreseeable that negligence in fulfilling
2 this duty can be the proximate cause of severe injury
3 and even death. False high reading may mask
4 significant hypoglycemia or may prompt excessive
5 insulin administration, leading to coma and possibly
6 death. Conversely, a false low reading can delay the
7 necessary administration of insulin, resulting in
8 hyperglycemia and its consequences. Therefore, I'd
9 like to focus my remarks this morning on the second
10 element.

11 And here's the question for this morning.
12 What conduct if any with respect to the use of blood
13 glucose meters by a hospital or healthcare
14 practitioner might reasonably be characterized as
15 negligence? Now, before going on to the specifics of
16 blood glucose meters, I'd like to discuss generally
17 how negligence is determined in malpractice cases. In
18 essence, the trier of fact ? usually the jury,
19 sometimes the judge ? measures the challenged conduct
20 against the so-called standard of care and decides
21 whether the conduct satisfies that standard. So how
22 is the standard of care determined?

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1 The approach varies somewhat from state to
2 state. Basically, however, the jury or judge hears
3 the testimony from expert witnesses for both sides.
4 It also considers other relevant authorities. And
5 those would include governing, legal and regulatory
6 requirements, pronouncements by government agencies
7 such as FDA, statements of knowledgeable private
8 organizations such as the American Diabetes
9 Association, practice guidelines issued by
10 professional societies such as the American
11 Association of Clinical Endocrinologists, the
12 manufacture's package insert where a drug or medical
13 device is concerned, and any other sources deemed by
14 the court to be reliable or authoritative.

15 I'll just digress at this moment to say that
16 because pronouncements by government agencies are
17 relevant to a malpractice consideration, any public
18 health alert or other notice by FDA can have
19 significant implications for a malpractice case. Now,
20 where the conduct at issue directly violates a
21 specific law or a specific violation, it is held in
22 many jurisdictions to be negligence per se. There's

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1 nothing further to be discussed. In all other cases,
2 where there's not a specific violation of a law or
3 regulation, the trier of fact evaluates all the
4 relevant inputs and determines what a reasonable
5 person or entity in the position of the defendant
6 should have done. That determination constitutes the
7 standard of care.

8 With that general summary as background, let
9 me move on to the issues raised by the use of point of
10 care blood glucose meters. At the outset, I don't
11 think there's any doubt that use of such meters would
12 as a general matter satisfy the standard of care.
13 It's true that results from meters may not be as
14 precise as results from blood assayed by a laboratory.
15 But absolute precision is not generally required, as
16 you all know, in the measurement of blood glucose.
17 The FDA has traditionally allowed a 20 percent
18 deviation when reference method glucose values are
19 greater than 75 milligrams per deciliter. While this
20 figure can be debated and is often thought to, should
21 be reduced, the 10 to 15 percent range generally seems
22 to pose little clinical problem. Moreover, bedside

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1 meters allow frequent monitoring and rapid reporting,
2 avoid multiple phlebotomies and cost less. For this
3 reason, their use is widely accepted.

4 Indeed, the 2010 standards of medical care
5 and diabetes, which was published by the American
6 Diabetes

7 Association and endorsed by the Joint
8 Commission, note as follows: Safe and rational
9 glycemic management relies on the accuracy of blood
10 glucose measurements, using point of care blood
11 glucose measures which have several important
12 limitations. I want to come back quite soon to the
13 last clause there, which is the several important
14 limitations. But for now, given this sort of
15 statement and the wide acceptance of blood glucose
16 meters, the use of such meters without more should not
17 give rise to any sort of malpractice action.

18 To get a little bit more controversial, I
19 don't believe that it is malpractice to use blood
20 glucose meters in tight glycemic control situations,
21 even though those devices have not been cleared by the
22 FDA for such a use, as long as the use has been

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1 clinically validated. The fact that a drug or device
2 has not been cleared for a particular use, means that
3 the manufacturer cannot market or otherwise promote it
4 in any way for that use. But it does not mean that
5 use of the drug or device for off-label purposes
6 constitutes negligence. In this connection, a 1982
7 FDA statement on use of approved drugs for unlabeled
8 indications is quite relevant.

9 Here's what the agency said in 1982. The
10 Food, Drug and Cosmetic Act does not limit the manner
11 in which a physician may use an approved drug. Once a
12 product has been approved for marketing, a physician
13 may prescribe it for uses or in treatment regimens or
14 in patient populations that are not included in
15 approved labeling. Such unapproved or more
16 presciently, unlabeled uses, may be appropriate and
17 rational in certain circumstances and may in fact
18 reflect approaches to drug therapy that have been
19 extensively reported in malpractice literature.

20 Now, this statement was made in the context
21 of drugs, but it applies equally to devices. Thus,
22 use of meters in tight glycemic control situations

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1 should not be regarded as malpractice to the extent
2 that the specific use is supported by peer-reviewed
3 medical literature or by clinical validation by the
4 practitioner.

5 Let me return now to the statement of the
6 American Diabetes Association to the effect that use
7 of blood glucose meters has quote, "several important
8 limitations." It is the use of the devices without
9 adequate regard for those limitations that will create
10 malpractice liability. And I have identified four
11 such limitations. You may have identified more or
12 less, but

13 I've identified four. Here they are:
14 interfering substances, system limits, equipment
15 malfunction and patient misidentification. I'm going
16 to address each of these limitations and consider
17 their malpractice implications. First, however, I
18 want to make an important point about blood glucose
19 meters.

20 To echo and distort the Declaration of
21 Independence, all meters are not created equal.
22 Depending on the chemistry and technology utilized,

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1 each brand of meter is subject to interference by
2 different substances, has different system limits and
3 has other unique characteristics. Thus, the most
4 basic advice that I would give to those responsible
5 for use of blood glucose meters in a hospital is this.
6 Know the limitations of the meters at your hospitals
7 and make adequate provision for those limitations.

8 Let me turn now to specific applications of
9 that general advice. Probably the most serious of the
10 limitations on blood glucose meters is the possibility
11 of reporting significantly inaccurate glucose levels
12 as a result of the presence of interfering substances.
13 Of these substances, the most widely publicized is as
14 you know, Maltose, and to a lesser extent Xylose and
15 Galactos. FDA has issued numerous notices and safety
16 alerts warning of problems caused by the presence of
17 non-glucose sugars in the blood for meters and test
18 strips based on ? I'm not going to get this right ?
19 based on glucose dehydrogenase, pyrroloquinoline quino
20 -- I'll just call it GDH-PQQ as everyone else does ?
21 the agency has warned of 13 patient deaths
22 attributable to false readings from GDH-PQQ

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1 technology. These deaths or severe injuries can be
2 caused by the presence of certain immunoglobulins,
3 abatacept and other sugar- creating substances, and in
4 patients receiving peritoneal dialysis solutions
5 containing Icodextrin, among other things.

6 Notably, the blood glucose meters that have
7 a problem with Maltose or other sugar interference
8 contain warnings, generally very prominent warnings to
9 that effect in their labeling. I understand,
10 moreover, that some manufacturers of these systems
11 offer education for hospital personnel on the
12 limitations of their devices. Thus, the issue of
13 interference by non- glucose sugars should be well-
14 known to lab directors, clinicians and hospital risk
15 managers. In light of the notices and safety alerts
16 issued by FDA on sugar interference, the warnings
17 about such interference in the package inserts and the
18 programs of manufacturers to educate hospitals about
19 such issues, it is highly likely that a death or
20 serious injury attributable to Maltose or other sugar
21 interference would be regarded as the result of
22 malpractice.

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1 It's somewhat surprising to me that I have
2 not uncovered any case in which this issue has been
3 considered or decided. I attribute this to the fact
4 that it's so cut and dry that probably these cases
5 don't even get litigated, they get settled. But the
6 general principle of malpractice law strongly suggests
7 that exposure in this scenario is of major consequence
8 -- I'm behind on my slides -- there's the basic advice
9 I gave you before. Know the limitations of the meters
10 at your hospital and make adequate provision for these
11 limitations. We talked about this. And as I just
12 said, a hospital at which a death or serious injury
13 attributable to Maltose or other sugar interference
14 occurred is likely to be found liable in malpractice.

15 For this reason, the lesson is clear. It is
16 essential to review the package insert of meters and
17 test strips used at the hospital to determine whether
18 they are GDH-PQQ-based. If they are, hospital staff
19 must be educated that the meters may not be used if
20 the patient is on an immunoglobulin or other drug or
21 biologic that produces Maltose, is receiving abatacept
22 therapy, is receiving a peritoneal dialysis solution

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1 containing Icodextrin, suffers from Galactocemia or
2 otherwise may have abnormal levels of non-glucose
3 sugars in the blood. If there is any doubt, if there
4 is any doubt whatsoever, the lab director or the
5 hospital should contact the manufacturer or otherwise
6 resolve the issue before permitting use of the system
7 on a patient. The importance of this practice cannot
8 be overstated.

9 Now, FDA is of course, performing a vitally
10 important public health service in warning hospitals,
11 practitioners and patients of the risks of falsely
12 elevated glucose results from GDH-PQQ test strips
13 where non-glucose sugars may be present. But given
14 the significant implications of its statements, the
15 agency must take care to be precise in what it says.
16 One statement that it made, which in my view may have
17 gone a bit far, was contained in a public health
18 notification dated August 13, 2009. In that
19 statement, in that notification, the agency made the
20 following statement, quote: "Avoid using GDH-PQQ
21 glucose test strips in healthcare facilities," end of
22 quote. Having told the world not to use these test

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1 strips in healthcare facilities, it listed categories
2 of patients for whom such strips should never be used
3 and it set forth steps that can be taken to address
4 the risks imposed by non-glucose sugar interference.

5 Now, the listing of the categories of
6 patients at risk had the recommendation of steps to
7 address the risk are extremely valuable and extremely
8 important. Moreover, in my judgment, they quite
9 properly increase the malpractice exposure of
10 facilities and individuals who ignore those steps.
11 But the advice to quote, "avoid using GDH-PQQ glucose
12 strips in healthcare facilities" as an absolute matter
13 may go too far. It encourages facilities who have
14 made a significant investment in certain kinds of
15 meters to discard those meters at substantial cost,
16 and it puts facilities at malpractice risk if an
17 adverse event were to arise with such strips for
18 reasons unrelated to sugar interference. In my view,
19 while it is extremely important that the agency warn
20 the public, warn practitioners, warn patients about
21 risks, it should be very careful to word its warnings
22 as precisely as possible.

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1 Now, in this connection, I would note that
2 there are other interfering substances that can skew
3 results. These include acetaminophen, oxygen, uric
4 acid, Vitamin C and L-dopa. There may be others but
5 those are the ones I know about. As best as I can
6 determine, FDA has not issued any notices or safety
7 alerts for these or other interfering substances.
8 That's probably because a deviation from accurate
9 results is generally less with these substances than
10 with Maltose. Moreover, I'm not aware of patient
11 deaths associated with false readings from
12 interference by the other substances. Nevertheless,
13 providers should be aware of interference by other
14 substances, particularly for patients on tight
15 glycemic controls.

16 Manufacturers of blood glucose meters test
17 for interference by a number of anilities. Any
18 identified interfering substance is generally warned
19 of in the package insert. In light of these warnings,
20 a hospital or practitioner that permits use of a meter
21 in a situation warned against in a package insert
22 risks malpractice liability to a patient who is

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1 injured or who dies as a result of incorrect therapy
2 based on a faulty reading. To be sure, failure to
3 follow the warnings on a package insert does not
4 constitute malpractice per se. That occurs only when
5 there is a violation of a specific regulation or
6 statute. But in most jurisdictions, it will
7 constitute strong evidence that the responsible
8 practitioner and the hospital have failed to meet the
9 standard of care. This fact underscores the need of
10 laboratory personnel and hospital risk managers to be
11 familiar with the package inserts of blood glucose
12 meters and to take appropriate steps to guard against
13 interference.

14 Now, the second important source of
15 potential liability is use of blood glucose meters
16 outside of system limits. It's very important that a
17 hospital know and understand system limits. Although
18 not as widely publicized as non-glucose sugar
19 interference, this issue has received more publicity
20 of late. At the end of last month, a manufacturer
21 recalled 14,000 test strips that led to false low
22 readings in some circumstances. While no injuries

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1 were reported, the recall highlights the fact that the
2 technology has limits.

3 System limits relate, among other things, to
4 transient temperature, the humidity to which the
5 strips are exposed, storage conditions and strip
6 expiration dates. Most if not all manufacturers build
7 in so-called fail-safes to lock out use of the meters
8 when the strip has been compromised or when conditions
9 are otherwise beyond the system's limits. However,
10 not every product has the same fail-safe feature.
11 Thus, it becomes important to understand the system's
12 limits, and they are generally set forth in the
13 package insert.

14 No system guards against false readings due
15 to all limits. For example, there can be a problem
16 with so-called open vial, the open vial issue. Once a
17 container or strips is opened, the strips remain good
18 only for a certain period of time, which varies from
19 manufacturer to manufacturer. Use of strips that have
20 been exposed to the air for more than this period of
21 time may result in erroneous readings. So as I say
22 here, it's very important for hospitals to have

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1 policies in place against use of meters, contrary to
2 system limits, and for practitioners to comply with
3 these policies.

4 Another example of a system limit is the use
5 of meters on patients with hematocrit values outside
6 the manufacturer's specified range. In patients with
7 a low hematocrit value, a meter may report false high
8 glucose levels. Different systems have different
9 capacities to guard against hematocrit distortion.
10 Accordingly, steps should be taken to avoid use of the
11 meters for patients with hematocrit values outside the
12 range specified in the package insert.

13 Moving to the third of the limitations,
14 blood glucose meters generally, absent an interfering
15 substance or a system limit issue, report results that
16 do not deviate more than 15 percent from the true
17 value. But as we all know, it's a universal truth
18 that machines and systems sometimes malfunction. If a
19 malfunction does occur and results in patient injury,
20 it is quite likely that a malpractice suit will
21 follow. The best way to limit malpractice exposure in
22 this area is to conduct QC in accordance with the

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1 manufacturer's instructions, or in the absence of such
2 instructions, on a daily basis. In making that
3 statement, I'm well aware that glucose testing is a
4 wave testing under CLIA. I'm not sure why, by the
5 way. Thus, federal law does not mandate QC on glucose
6 meters. However, both the Joint Commission and the
7 College of American Pathologists, as part of their
8 respective accreditation programs, require QC in this
9 area.

10 If a hospital or a practitioner were sued,
11 the Joint Commission and the CAP standards are likely
12 to be put into evidence. Likewise, the package insert
13 will almost certainly be introduced, and there will be
14 testimony on the importance of QC. Thus, despite the
15 wave status of this test under CLIA, malpractice
16 considerations counsel strongly in favor of performing
17 appropriate QC.

18 The final area of potential malpractice
19 liability relates to patient misidentification. The
20 Institute of Medicine report, To Err is Human, spoke
21 about the incidence of adverse events due to human
22 error. The Joint Commission has required that test

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1 results be noted in the patients' chart and associated
2 with the correct patient. One can readily imagine the
3 malpractice consequences, to say nothing of the human
4 consequences, if insulin administration to patient A
5 were based on patient B's results. Some manufacturers
6 incorporate patient identification into their meters.
7 A few do not. Many problems stemming from point of
8 care testing are the results of human error, not
9 instrument error. It is important, therefore, that a
10 hospital which uses meters without a patient
11 identification feature makes sure that it has a system
12 in place to avoid patient misidentification.

13 I want to sum up now in two ways. First, I
14 want to say that use of point of care glucose meters
15 is well within the standard of care. Each brand of
16 these meters has limitations, which should be
17 understood and addressed if malpractice risks are to
18 be minimized. Having said, that, I'm now going to
19 recommend ten steps to guard against malpractice
20 liability from the use of blood glucose meters. Given
21 that mosaic number of ten, I'm going to refer to the
22 as the ten commandments of blood glucose. I'm not

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1 going to do it in biblical text, however. I was
2 tempted to do it, but thought it would be a little bit
3 artificial.

4 Here there are, the ten commandments of
5 blood glucose meter use. For meters that use GDH-PQQ
6 technology, educate staff and patients about the
7 potential for falsely elevated glucose results in the
8 presence of Maltose or other non-glucose sugars. Make
9 sure that the meter is not used on patients who are
10 having therapy or will have a condition that produces
11 non-glucose sugars. For all meters, be aware of the
12 manufacturer's instructions for proper use, storage
13 and handling of strips and meters and have policies in
14 place and enforced to follow those instructions.
15 Three, train all responsible personnel on the proper
16 use of the meters, document the training, and alert
17 all such personnel to relevant FDA pronouncements and
18 any updates or notices issued by the manufacturer.
19 The fourth commandment. As the FDA has advised,
20 consider using drug or action alerts in computer order
21 entry systems, patient profiles, and charts. Fifth,
22 know the hematocrit levels at which the meter

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1 functions effectively. Don't use the meter on patients
2 whose hematocrit levels or outside the specified
3 range. Six, perform QC on each meter as recommended
4 in the package insert, or at least once a day. Seven,
5 as the FDA has also counseled, consider periodic
6 verification of glucose meter result with laboratory-
7 based glucose assays, particularly in tight glycemic
8 control situation. You recall I said that I didn't
9 think it was malpractice to use glucose meters in
10 tight glycemic controls situations, but that was
11 subject to clinical validation, and certainly
12 comparing the results and verifying the results by
13 comparison with laboratory- based glucose-based assays
14 is a very good idea.

15 The eighth commandment. Implement a system,
16 either through a fail-safe system on the meter or
17 through general hospital protocols to ensure that
18 there are no patient misidentification errors. The
19 ninth commandment. If there is any issue regarding
20 use of a particular meter for a particular patient,
21 don't use the meter until you are satisfied that use
22 on the patient is safe. And the final commandment

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1 really sums it all up and harkens back to the second
2 commandment. Most generally, know the limitations of
3 any meter as set forth in the package insert or as set
4 forth in FDA announcements, and make sure that the use
5 conforms to these limitations. If you harken
6 diligently onto those commandments, I think that
7 patients will get the benefits of point of care blood
8 glucose meters, and manufacturers, hospitals and
9 practitioners will minimize their risk of malpractice
10 liability. Thank you.

11 MR. BIERIG: I'm hoping ? what Courtney
12 didn't say is I also teach health law and policy at
13 the University of Chicago, so I love getting
14 questions.

15 DR. HARPER: Yes. We do have a little bit
16 of time for questions, and I'm going to start it off,
17 because I have one or -- maybe it's kind of two
18 questions.

19 MR. BIERIG: I was getting worried when I
20 saw you taking notes there, Courtney.

21 DR. HARPER: Well, my question is, it's very
22 clear that where FDA issues of public health

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1 notification or something like that, that that is a
2 clear message to practitioners that it might be
3 malpractice, if that still resulted in a death or
4 serious injury. But what about contraindications and
5 label limitations. I wasn't as clear as that from
6 your talk, and I'll give you an example. Most of the
7 meters that we clear actually limit against using
8 critically ill patients. So I wonder, where you say
9 that where's there's a clear limitation or alert, it
10 would be malpractice but it wouldn't be necessarily be
11 malpractice to use if it it's accepted. Where does
12 that line get drawn?

13 MR. BIERIG: That's an excellent question.
14 Acting contrary to a package insert, as I said in my
15 presentation, is not in and of itself malpractice.
16 But there's no doubt that a plaintiff's malpractice
17 attorney would introduce the package insert into
18 evidence, would argue that use contrary to the package
19 insert is strong evidence of malpractice, and then it
20 would be up to the defendant to explain why although
21 that is required by FDA, it really does not reflect
22 the standard of care. So there would be expert

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1 testimony to the contrary or medical journal articles
2 to the contrary. But there's no question that the
3 fact that that kind of limitation appears in the
4 package insert would be a very important fact in a
5 malpractice action.

6 DR. HARPER: Are there any examples about
7 how that's gone one way or the other that are similar?

8 MR. BIERIG: Not in this context. As I
9 said, I can't find -- I searched and I had two or
10 three other people searching to find cases involving
11 malpractice, reported malpractice decisions in the
12 context of blood glucose meters, and we couldn't find
13 any. And I suspect that's not because there haven't
14 been any, but because when the defendant or the
15 insurance company representing the defendant sees the
16 case, they figure it's best to just pay rather than to
17 litigate. That's my guess.

18 DR. HARPER: What about for other medical
19 devices? Are there any ?

20 MR. BIERIG: Yeah, there are cases to that
21 effect.

22 DR. HARPER: And then the second part, which

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1 you may have answered a little bit, you mentioned --
2 they said if FDA hasn't released a safety alert on
3 some of the other interferences -- and there have been
4 deaths from dopamine, there have been deaths in
5 critically ill patients, there have been deaths in
6 patients with renal failure. SO I don't know that
7 everyone knows that, because FDA didn't actually do a
8 public alert. Does that impact these types of cases?

9 MR. BIERIG: Well, the fact that the agency
10 hasn't issued an alert would certainly be used by the
11 defendant in a case like that. Let's say there was L-
12 dopamine interference, and then there was an action
13 against the hospital or a clinician. They would say,
14 we weren't negligent; we had no basis for knowing that
15 that was a problem so of course we didn't check. So
16 the fact that the agency hadn't issued an alert would
17 be a fact. Now, if there's literature out there --

18 DR. HARPER: It's in the labels.

19 MR. BIERIG: Or it's in the labeling,
20 personally I would rather be on the plaintiff's side
21 of that case, if it's in the labeling.

22 DR. HARPER: Well, this is very interesting

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1 to me, because I don't know anything about this area.

2 Thank you.

3 MR. BIERIG: That shouldn't stop you.

4 DR. STOREY: Andrew Storey from Cangene.

5 It's a great presentation. I liked your commandments.

6 They should be easier to follow than the other set.

7 MR. BIERIG: However, unlike other set, they
8 are mutable, so I'll --

9 DR. STOREY: But I did have to take
10 exception with the first commandment, which is that
11 GDH-PQQ meters should not be used for any patients
12 that are being provided Maltose-containing products.
13 Because there are several licensed Maltose-containing
14 products out there that contain Maltose in such low
15 concentrations that they do not provide any
16 interference with those meters.

17 MR. BIERIG: I accept that. This may be why
18 Moses had to go up a second time to -- that's a very
19 valid point, and I may -- having criticized the FDA
20 for going too far, I may have been slightly inaccurate
21 myself. I think that's a valid criticism.

22 DR. STOREY: It really depends on the

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1 concentration of Maltose in the product and the dose
2 of the product.

3 DR. BIERIG: I accept that, and I should
4 modify that and will.

5 DR. BEASTON: Patricia Beaston, FDA. How do
6 you describe or define widely published? A lot of
7 times somebody will come out with one big study and
8 then everybody jumps on the bandwagon and they start
9 doing that. But the patients aren't always well-
10 described. The protocol isn't complete, but people
11 start following that recommendation. And as we'll
12 discuss more and was discussed yesterday with tight
13 glycemic control, it seems to be a moving target. So
14 when you want to defend somebody using off-label
15 products, how do you defend that as widely published?

16 And then the second question is, you speak
17 to hospitals and practitioners, but if you're a
18 practicing physician not in the hospital and you have
19 patients who might be using 30 glucose meters and you
20 have no way of knowing the individual performance
21 characteristics of those meters, what's your liability
22 when you tell your patient to use a glucose meter, and

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1 they may be getting medications from five different
2 physicians?

3 MR. BIERIG: Okay, let me try to answer both
4 of those. Stand up there; don't go away. How do I
5 define widely publicized? Well, I don't define it.
6 In terms of the defendant, if there are studies out
7 there that the defendant has looked at and considers
8 reliable, that is the basis for a defense that the
9 conduct by that practitioner, that hospital, whoever
10 it is, was not negligent. If there's an article
11 that's published in JAMA or the New England Journal or
12 in a Journal of Clinical Endocrinology, sure, it's
13 subject to debate. That's how science and medicine
14 advance. But if it makes sense, if it seems like it's
15 a ? it's certainly going to be peer-reviewed. If it
16 seems like it's well-controlled, I think that provides
17 a basis for a defense. Remember, at the end of the
18 day, one of the amazing facts about our legal system
19 is, these very complicated medical questions get
20 decided by a jury of people who don't have the
21 foggiest clue of what's going on.

22 I give a speech on why doctors hate lawyers

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1 -- it's actually excellent. But it's interesting, in
2 medicine when you talk about peer review, you talk
3 about review by other physicians or by other Ph.Ds.
4 That's peer review. In law, when we speak of a jury
5 of one's peers, those peers are truck drivers and
6 elementary school teachers and unemployed people and
7 students. And so these decisions get made by people
8 who really don't understand not only the nuances but
9 even the basics of these issues. So the fact that
10 something has been published is a fact that gets put
11 to the jury and that the jury has to decide. That's
12 my answer to your first question, whether it's
13 satisfying or not, that's my answer.

14 The answer to your second question is, it's
15 a real problem. Fortunately, my talk today was on
16 liability of hospitals and practitioners at hospitals.
17 But for a practitioner who's seeing as you say in the
18 office, may people who use blood glucose meters and
19 they have very different meters, I think it's probably
20 an extremely good idea for the physician to put out
21 sort of a two-page, one or two-page information sheet
22 for the patient in which the practitioner generally

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1 describes various meters and says, if you have this
2 condition or that condition or the other condition,
3 you might consider not using this meter or using that
4 meter, that might help. Because as you say, you don't
5 know all the medications that you're patient is on,
6 you may not know exactly which meter the person has,
7 they may switch without your knowing. So you're in a
8 difficult bind.

9 But I think having some kind of patient
10 education material is a good idea. That's not to say
11 if you don't have that that you're necessarily going
12 to be liable in malpractice, but in terms of best
13 serving the patient, I think giving the patient some
14 idea of the kinds of considerations that we're talking
15 about, only in very lay non-technical terms, is
16 probably a good idea. That's my idea.

17 DR. BEASTON: Thank you.

18 DR. HARPER: Unfortunately, we don't have
19 addition time right now for questions, but we will
20 bring Jack back up for the Panel discussion later if
21 he's still around.

22 MR. BIERIG: He will not be around.

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1 DR. HARPER: So you can talk to him at the
2 break.

3 MR. BIERIG: Okay, you can talk to me at the
4 break. Thank you very much.

5 DR. HARPER: Thank you. So just one
6 accouchement before we start with Session 3. So
7 anybody who needs to go to the airport later, we
8 actually have a sign-up sheet outside at the
9 registration desk, and you can sign up for taxis to
10 the airport this afternoon. So I encourage you all
11 during the break to go and sign up for times, if you
12 all need to get to the airport.

13 Now, it's my pleasure to introduce Irl
14 Hirsch, who is the moderator for Session 3, for Tight
15 Glycemic Control. Dr. Hirsch is a professor of
16 medicine and holds the Diabetes and Teaching Chair at
17 the University of Washington School of Medicine,
18 Seattle. He's interested in new technologies for the
19 treatment of diabetes, particularly those involved in
20 insulin therapy. So we welcome Dr. Hirsch.

21 DR. HIRSCH: Great. Thank you. Thank you
22 very much and welcome to Session 3. Couldn't take

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1 this opportunity without having a few introductory
2 comments before we get started. Want to put an
3 historical overview into where we are as we move into
4 this Session 3. Pre-1980s -- many of you were around
5 then, seen patients. You all remember the topic of
6 fractional urine testing, as I see some heads nodding,
7 and the introduction of sliding scale insulin, which
8 by the way, I could first find mention in in a
9 textbook from the early 1940s in a surgery textbook.
10 And this is what we did. Many of you remember this.

11 And then the introduction of bedside
12 capillary testing in the 1980s, however, did not
13 change the culture of sliding scale insulin. But
14 until 1987, bedside glucose testing used enzyme-based
15 photonic methods, mostly by measuring change and light
16 reflectance of a dye-containing strip resulting in a
17 glucose oxidation reaction. And today, as you know,
18 almost all finger stick testing is performed with
19 electro chemical methodologies, which allows smaller
20 volume of blood and faster tests.

21 Furthermore, as we move down this historical
22 overview, there has been little attention to glucose

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1 control in the hospitals until the randomized control
2 trials and retrospective data by some of the people in
3 the room today, including Van den Berge, Furnary,
4 Krinsley, and many others suggested that TGC or tight
5 glucose control, should be the standard of care. And
6 then of course, ADA, AACE, Society of Hospital
7 Medicine and many other societies around the world
8 created standards for in-patient targets, particularly
9 in the
10 ICU.

11 So what happens. Well, the RCTs for glucose
12 controlled and other settings, such as myocardial
13 infarctions, MICU and sepsis, did not show that tight
14 glucose control improved outcomes. And then last
15 year, we had the announcement of the study NICE-SUGAR,
16 which showed attempts that tight glyceimic control may
17 actually worsen outcomes. So while tight glyceimic
18 control consistently showed increases in hypoglycemia
19 rates, independent of these studies, new research
20 showed that hypoglycemia results in more severe
21 arrhythmias than we had appreciated, in addition to
22 the fact that hypoglycemia in and of itself led to

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1 inflammation on top of the known CNS side effects. So
2 hypoglycemia, bad.

3 And then last year in the New York Times
4 there was an article that pointed out that glucose
5 meters in general, including those in the ICUs, are
6 not as accurate compared to the perception on top of
7 the fact that there are important interferences, which
8 we just heard about, noted for many types of meters.
9 And the article that was quoted in that New York Times
10 article actually comes from the CDC, which showed up
11 to a 32 percent variation in blood glucose results.

12 So the main questions for us now is what is
13 the impact of tight glycemic control if it can be done
14 uniformly in both academic and community hospitals
15 without hypoglycemia? Is it possible to do this with
16 today's bedside glucose technology? And do we need
17 better technology for bedside blood glucose testing?
18 I think these are some of the fundamental questions.
19 And finally, what is the role in the ICU of continuous
20 glucose monitoring, and would tight glucose control
21 efforts improve? I for one think it very well may.
22 These are just some of the devices that are now being

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1 tested for intravascular testing. And again, the
2 question is, will tight glycemc control be possible
3 in most hospitals once this technology is available?

4 I was provided a list of questions I want
5 you to think about with our speakers and our
6 discussions this morning as we go through this Session
7 3 about TGC in the hospitals and ICUs, and think about
8 these. First, what is your estimate of the percentage
9 of hospitals that use tight glycemc control in the
10 United States. What factors must be considered as
11 physicians weigh the risks and benefits of using blood
12 glucose monitoring in hospitals settings, and how do
13 we balance this need for faster turnaround with known
14 inaccuracies of meters? What types of issues
15 determine whether a patient will or will not be kept
16 on a tight glycemc control protocol? And how often
17 do users, both in the hospital and at home, actually
18 see or read the labeling so they are familiar with the
19 limitations of these meters? Ms. Hanson will be
20 discussing risk mitigation in hospital settings later,
21 but do you believe hospital staff are trained and
22 certified to ensure they understand these limitations?

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1 And how do thoughts of the liabilities that exist in
2 hospitals influence decisions to follow these TGC
3 protocols? Do the cost or reimbursement for strips
4 themselves affect the way meters are used in hospitals
5 in this country? And finally, what types of
6 reimbursement incentives might be developed by payers,
7 whoever the payer may be, for manufacturers who
8 develop more accurate and reliable blood glucose
9 monitoring systems?

10 So what we will be doing this morning is
11 looking at various aspects of TGC in the hospital,
12 first from an FDA perspective with Carol Benson, then
13 a payer perspective with Jim Rollins. Then we will be
14 hearing after the break about advantages of tight
15 glycemic control in the hospital by Rich Bergenstal,
16 then why tight glycemic control may not be appropriate
17 by Dieter Mesotten. And finally, I will be talking
18 about current practice and experiences with TGC in
19 hospital settings.

20 So that's by way of introduction. I would
21 now like to introduce our first speaker, who's going
22 to be talking about regulatory challenges for safe use

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1 of blood glucose meters in hospital settings, will be
2 Carol Benson, who is an Associate Director of the
3 Division of Chemistry and Toxicology Devices in the
4 Office of In Vivo Diagnostic Device Evaluation and
5 Safety. Carol?

6 DR. BENSON: Thank you. This morning I am
7 going to be talking about the regulatory challenges
8 for the safe use of blood glucose meters in hospital
9 settings. This is an overview of what I'm going to be
10 talking about. First I'm going to be talking about
11 the intended use that the manufacturers seek when they
12 come to FDA for clearance with their blood glucose
13 meters. What are the implications under CLIA for the
14 clearance of blood glucose meters? Whether FDA's
15 acceptance criteria for accuracy. Whether some issues
16 that are specific to the hospital glucose meters and
17 test strips. We look at these as a whole system, not
18 just the meters, but the meters in combination with
19 the test strips. And also, I'm going to be reminding
20 us about the post market issues and what they're
21 telling us.

22 When manufacturers come to FDA for clearance

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1 for their glucose meters, they seek clearance for
2 marketing for both lay users and for professionals.
3 When we have a clearance for lay users, we consider
4 this an over-the-counter device. So you may be
5 wondering, why do manufacturers seek clearance for
6 both lay users and home users? Well, according to the
7 CLIA regulation, 493.15, all glucose monitoring
8 devices that are cleared by FDA for home use are
9 waived by regulation. So when the manufacturer gets
10 their clearance by FDA, they also get a waived device.
11 They get a CLIA categorization for a waived device.

12 What are the implications of a CLIA waived
13 device? Well, anybody can use the device in any
14 setting. You get a certificate from the Centers for
15 Medicare and Medicaid Services, and you follow
16 manufacturer's instructions. You need to follow the
17 manufacturer's instructions for testing and for
18 performing external quality control. Now, the
19 manufacturer needs to recommend what type of external
20 quality control to do because under CLIA, there are no
21 requirements to do external quality control for a
22 waive device. And also, there's no requirements to

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1 perform any proficiency testing. And there's no
2 requirements that the personnel need to be trained.

3 There is a way, though, to obtain a CLIA
4 waive device other than seeking clearance for over-
5 the- counter devices. In 2008, FDA published a
6 guidance here for recommendations for waiver
7 applications for manufacturers of in vitro diagnostic
8 devices. This is on their Web site. These studies,
9 though, are generally more robust than the typical
10 type of studies that are done for lay users for an
11 over-the-counter device. The requirements generally
12 are that 360 samples are tested. We ask that they be
13 tested in a minimum of at least three sites, that the
14 testing be performed by the typical type of people in
15 the waived settings, and that they test this
16 information over time, a minimum of two weeks.

17 The accuracy criteria for blood glucose
18 monitoring devices under the CLIA waiver studies is
19 tighter than the ISO 15197 standard. Here, we are
20 looking at 95 percent of the results to be within plus
21 or minus 15 percent of the values that are equal or
22 greater to 75, or plus or minus 12 milligrams per

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1 deciliter for values that are under 75. CLIA waiver
2 studies are also, the evaluation is we look at the
3 other 5 percent of the values. The ISO criteria,
4 remember, we don't know what happens to those other 5
5 percent, but when we wrote the CLIA waiver guidance,
6 we set up some kind of a limits, called limits of
7 erroneous results. And we see, where do those other 5
8 percent of the results fall.

9 So we look at these other 5 percent of the
10 results, and we have these limits set up as to where
11 we think, that if results fall in that category, they
12 would be so egregious that they would cause harm to
13 the patient. And in addition, we ask the
14 manufacturers to perform flex studies. These are
15 studies in which the devices are stressed. Tried to
16 find out, what could the user do that could cause an
17 error in the device. Some of the things we learned
18 yesterday, we know that perhaps we can't test for.
19 Like, if somebody leaves the vial strips open, they
20 don't wash their hands. That's not something that they
21 can stress the device to detect. But supposing that
22 the device has an operating temperature. They can

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1 stress the device to see, does the operating
2 temperature they recommend -- I mean, does it fail
3 just one degree past that recommended time or does it
4 fail two digress before that time?

5 We have regulatory challenges when we clear
6 meters for both over-the-counter for lay users and for
7 healthcare professionals, because many of these meters
8 we know are designed for health professionals only.
9 These meters are rather large, they have docking
10 stations, they have barcode capabilities, they
11 transmit data, they have quality control lockouts, and
12 they have large memory capacity to store data -- all
13 the things that health professionals want. But the
14 manufacturers seek clearance for over-the-counter.

15 Also, the regulatory challenges for us are
16 that we use the same minimum accuracy criteria for the
17 lay user studies as we do for the healthcare
18 professionals. We learned yesterday that about 100
19 patients are tested for lay users, and their results
20 are compared to reference methods, such as the YSI.
21 And then the health professionals test 100 patients
22 and their results are compared to the YSI. However,

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1 in these studies when we seek clearance for both,
2 generally the same patients are tested for the
3 studies. The laypersons test first and then the health
4 professionals test the laypersons. These are not
5 being tested on sick hospitalized patients. They
6 don't see that data.

7 Also, we do use the minimum ISO criteria
8 from the ISO 15197 standard. And I thought about
9 giving us a quiz today, because I think by now we can
10 all say this in our sleep -- that we're looking at 95
11 percent of the results that need to be within plus or
12 minus 15 milligrams per deciliter for values that are
13 less than 75 or plus or minus 20 percent for things
14 that are greater than 75 milligrams per deciliter.

15 The use of this criteria, though, brings us
16 regulatory challenges, because we know that there can
17 be large differences between the meter and the
18 reference method. For example, we know that if a
19 value is 60, by the reference method the meter can
20 vary from 45 to 75 and be considered acceptable. If
21 it's 200 on the reference method, the meter may vary
22 as much as 160 to 240 and be acceptable. And only 95

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1 percent of these results need to meet the minimum
2 accuracy criteria. So if 100 are tested, only 95 meet
3 it. What happens to the other 5 results or the other
4 5 percent? They're not evaluated.

5 We know that the ISO 15197 standard is
6 written for meters and test strips that are designed
7 for lay users only. Should they be tightened for lay
8 users? We talked about that a lot yesterday. We know
9 that this criteria are broader than the College of
10 American Pathologists requirements for laboratory-
11 based systems, which are 10 percent, or 6 milligrams
12 per deciliter, whichever is greater. But currently,
13 FDA applies this criteria to all meters and test
14 strips, except those that come through for CLIA
15 waivers for studies. Are these too broad for hospital
16 use meters to be safe and effective? That is the
17 question.

18 We heard also about the problems with
19 interfering substances and that these are cumulative
20 in the patient, hematocrits, drugs that the patient
21 may be on, dopamine, acetaminophen; do they take
22 Vitamin C or they have a high lipid? Has the

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1 temperature of the strips been compromised? Are we at
2 a high altitude place? Do we have humidity? So if
3 each of these affects the glucose by 10 percent and
4 they're evaluated separately, what is the cumulative
5 effect for the patient? Well, if we were to add all
6 these up, I'm not sure we actually know what the
7 cumulative effect is for the patient.

8 Hospital patients bring challenges, because
9 they're usually sick. They're dehydrated, they may be
10 in shock, be on oxygen, and they probably have
11 different hematocrits from patient to patient. And
12 these hematocrits might not necessarily be known at
13 the time of the testing. Probably are on multiple
14 drugs. We don't know how they affect the system. They
15 may be patients whose glucose values are changing
16 rapidly. And they're tested with multiple meters by
17 multiple users, which introduce error. Therefore, the
18 patients are treated immediately, whereas the lay use
19 person, they test their blood glucose, they have a
20 chance to look at the value, and they can decide if
21 they need to act on that value. Hospitalized patients
22 are tested and treated.

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1 And more importantly, what are the
2 consequences of hospital patients being tested with
3 multiple meters? From this recent article in 2009, we
4 find that hepatitis B virus infections are associated
5 with blood glucose meters, and they're increasing in
6 the United States. And it may be a totally unaware
7 problem. These meters need to be designed so that
8 they can be disinfected multiple times. Hospital
9 patients, according to another article we know, may
10 also be subjected to insulin dosing errors. If we
11 have a 20 percent total error, we can have greater
12 than 30 percent of the insulin doses can be different
13 from those that were intended, and we might miss a
14 significant number of hypoglycemic events.

15

16 The regulatory challenges we face with
17 hospital meters are, what is the intended use once it
18 gets to the hospital? It may be for that which is
19 different from which it's being cleared. It may be
20 being used for tight glycemic control. And what type
21 of accuracy from the meters is needed to achieve that
22 type of intended use? We've heard a lot about the

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1 interferences that could be present in hospital
2 patients -- Maltose, talked about drugs, oxygen,
3 dehydration. They could be in DKA. And there could be
4 a total unawareness of the user of these potential
5 interference or limitations in the labeling.

6 Currently, the challenges we face with
7 labeling are that the labeling for the healthcare
8 professionals is the same labeling that we use for the
9 laypersons. We add an additional section for
10 healthcare professionals only. And in this we have
11 though the same limitations. And the limitations that
12 we put in for glucose meters are not for use on
13 critically ill patients, those in shock and
14 dehydrated. We put the accuracy criteria of the 15197
15 standard as it's requested by the tables in that
16 guideline. The one problem with the labeling in
17 hospital systems it that probably the labeling is not
18 right next to the meter. The nurses have a day job.
19 They may not necessarily have read the manual. They
20 may not necessarily understand the limitations of the
21 labeling, and do they know when to test quality
22 control materials? If some of these meters have

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1 quality control lockouts, then they're reminded when
2 to test for quality control.

3 We believe that for safe and effective use
4 of the hospital meters, that we will need technology
5 improvements. We will need tighter accuracy criteria.
6 We would like to have less interference from drugs and
7 hematocrit and oxygen and altitude and all the things
8 that could be cumulative for the patient, and less lot
9 to lot variability. When devices are submitted to
10 FDA, three lots of test strips are evaluated in the
11 studies. But after the device is on the market, it's
12 up to the manufacturer to have lot release criteria
13 that they monitor. Lockouts are wonderful for quality
14 control. Can they also detect expired reagents? We
15 know that we can't detect people leaving the test
16 strip vials open for longer periods of time than is
17 recommended. And they need to have cleaning
18 procedures that would prevent infections, such as
19 hepatitis.

20 Yesterday Courtney presented all the
21 information about the post market signals, but I
22 wanted to remind us that many of these signals are

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1 coming from hospital use meters. We have over 12,000
2 reports. But we also learned that the denominator is
3 very large for glucose use. We have though, 100
4 deaths that have occurred from 1992 to 2009. But
5 also, Courtney gave you the Web link, because anyone
6 can report problems with glucose meters. Lay users
7 can as well.

8 In summary, I'd like to say that
9 manufacturers seek clearance for both the lay user and
10 the healthcare professional. And why they do this.
11 Why does the impact of a clear waived device on
12 glucose meters? And that FDA's minimum acceptance
13 criteria are tied to an ISO 15197 standard that's
14 designed for lay users. That hospital meters cause
15 problems because they're used on multiple patients and
16 tested by multiple users. They're also used on
17 patients who could be critically ill. They could be
18 on many drugs, have different hematocrits, and they
19 present infection control issues for us. And our post
20 market signals are telling us that there are some
21 problems with glucose meters, but we know that anyone
22 can report these problems, and we do encourage them to

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1 do so. Thank you for your attention.

2 DR. HIRSCH: You can step to the microphone
3 and introduce yourself for questions. I guess I have
4 a tiny itsy bitsy question for you. And that is --
5 and maybe you alluded to this, but the question still
6 remains to me anyway, especially in the hospital, what
7 should the standard be? You showed us what they are
8 now. You showed us the huge variability in glucose
9 levels that meet the standard. Should the standard be
10 changed?

11 DR. BENSON: I think that's the question
12 that we're dealing with right now. We're asking for,
13 what are appropriate acceptance criteria for use of
14 meters in hospital settings?

15 DR. HIRSCH: And what is your opinion of
16 that?

17 DR. BENSON: Well, I think we believe that
18 they need to be tightened.

19 DR. HIRSCH: Okay. Yes, front microphone.

20 MS. HERTEL: Yes, Connie Hertel from
21 AgaMatrix. I was wondering if you could comment on
22 labeling of the system kits regarding accuracy; for

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1 example, proven accuracy, high accuracy, et cetera?

2 DR. BENSON: We don't like to have patients,
3 or manufacturers to infer that their devices are
4 better than another device. Because what we do is
5 we're comparing the performance of that device to a
6 recognized reference standard. The ISO 15197 has a
7 table that is suggestive of how to display the
8 performance. We have included that table in the
9 labeling, but we don't want someone to say that my
10 device is more accurate than another device, or more
11 accurate than what are current standards.

12 DR. HIRSCH: Next?

13 DR. HELLMAN: Hi. My name is Richard
14 Hellman. I'm a practicing endocrinologist. The reason
15 why I think you are talking about needing to tighten
16 the standards of accuracy in hospital settings is
17 because of the illness, the severity of illness, and
18 the comorbidity conditions that the patients often
19 have.

20 But in fact, there are many settings in
21 which there are patients who are very vulnerable: a
22 patient with stage 5 renal failure in dialysis units,

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1 people in intermediate units, people in long-term
2 care, people with multiple comorbid conditions, people
3 who have ketoacidosis or are seen in the doctor's
4 office. Why would not the meter accuracy need to be
5 better for all of those people to protect the patients
6 with a similar comorbid or severity of illness?

7 DR. BENSON: I think we are asking that
8 accuracy standards be tightened for all glucose
9 meters, for whether they're being used over the
10 counter or they're being used in any healthcare
11 setting.

12 DR. HELLMAN: I think the goal is to protect
13 the patient, and if the vulnerability of patients
14 suggests an urgency to correct, it would seem that
15 since vulnerable patients are found throughout the
16 system, a more general approach would be appropriate.
17 Thank you.

18 DR. BENSON: Okay.

19 DR. PINKOS: Can I ask you a question? Do
20 you believe that the performance requirements should
21 be equally tight for home users as in hospitals?

22 DR. HELLMAN: That's a very important

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1 question. I think the real problem is actually making
2 that happen. Because the public actually are less
3 knowledgeable about the meters, and the issue of how
4 to properly educate people in their use is really one
5 that we really haven't begun to grasp. But in fact,
6 if the goal is to protect people and the key is
7 getting accurate information, I think there needs to
8 be a way in which we come to grips with the reality
9 that wherever the person is, they need to have
10 something to rely upon. And whether it be a patient
11 with Type 1 diabetes getting into their car ? and you
12 have data on that, as to the high frequency of errors,
13 or others -- I think providing people with something
14 that is accurate, it will save lives. And I think we
15 probably need to grapple with that, even though it's
16 more difficult.

17 DR. HIRSCH: Next question, please?

18 DR. SOLDI: Good morning. Monnett Soldo
19 from OptiScan again. Dr. Harper started by saying
20 that perhaps we will think about what we talked about
21 yesterday and come back with some additional thoughts.

22 Late yesterday I brought up the question of

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1 whether interferences should be considered as part of
2 the accuracy spec itself or not. In other words,
3 should we even be talking about accuracy in the
4 absence of dealing with interferences? And I would
5 argue even more strongly in an ICU setting. We have
6 over 1,400 points from ICU patients, and some of these
7 people are very sick, with multiple system organ
8 failures and sepsis and so on. And from our
9 experience, it would be a rare instance to find
10 something in ICU setting that didn't have a drug on
11 board. And frankly, as much as I would like to
12 consider tightening this spec, it's not obvious to me
13 that people can meet the current spec in the face of
14 those interferences.

15 So I would argue very strongly that we need
16 to demonstrate that we're actually even meeting the
17 current spec as well as having the discussion on
18 tightening it across the board. I think it's
19 important. If you're not taking into account
20 interferences, then frankly in an ICU setting, I don't
21 know what we're doing.

22 DR. BENSON: I think we would concur with

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1 you.

2 DR. HIRSCH: Thank you. Next question,
3 please?

4 MS. HERTEL: Hi, Connie Hertel again, from
5 AgaMatrix. Again, getting back to the labeling.
6 Since I do the submissions, I'd like a more definitive
7 answer if you don't mind, in that if we do a
8 submission with that type of labeling, will it be told
9 to us to remove it?

10 DR. BENSON: Yes.

11 MS. HERTEL: And is that against the whole -
12 - all manufacturers?

13 DR. BENSON: We would like to -- we apply
14 that to all manufacturers, because we would be getting
15 into superiority claim wars. So that's why we'd like
16 to use the standard recommended table and how to
17 display accuracy that's from the ISO standard.

18 DR. HARPER: The data we get do not in any
19 way give anyone the ability to claim that they're more
20 accurate than another meter. Those studies aren't
21 done.

22 MS. HERTEL: Thank you.

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1 DR. HIRSCH: Last question?

2 DR. CEMBROWSKI: Under the influence of wine
3 last night, but for laboratorians who evaluate
4 periodically new lots of either Live Scan, reagent, or
5 growth reagent, we thought that it is possible for
6 these manufacturers to manufacture lots that are
7 within plus or minus 12-1/2 percent. So we think --
8 we would urge the FDA to contemplate this, for
9 hospital patients, the new lots that should be
10 approved, 95 percent of the observations should be
11 within plus or minus 12.5 percent. It is doable, but
12 companies would have to stretch to produce this
13 product.

14 DR. BENSON: Thank you.

15 (Pause.)

16 DR. HARPER: So, we are have having to
17 change laptops for the next presentation, so we have a
18 little bit more time for questions or discussion on
19 this topic or some of the topics we discussed
20 yesterday.

21 DR. CHRISTENSON: Rob Christenson from
22 University of Maryland. I have a question about

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1 training actually. Dr. Harper yesterday mentioned
2 this issue with GDH and PQQ and sort of asking how
3 maybe we can better communicate, and I think the issue
4 about training for glucose meters in hospitals and all
5 the issues that come up with those. And I wonder if
6 there is an evidence base that shows what practices
7 work well and what practices don't work as well, so
8 that it might give us some guidance as to how we can
9 best go about those things. There's an effort now at
10 the CDC to come up with laboratory medicine best
11 practices, and it might be a good way of giving some
12 guidance as to what works best.

13 DR. HARPER: We'd be really interested in
14 hearing about that from CDC or any group actually.
15 Actually, later this afternoon this may be a good
16 question for Dawn Hanson. He's going to be talking
17 about risk mitigation in hospitals. So she may have -
18 - I don't want to put Dawn on the spot, so it's okay
19 if we don't hear from this, but I don't personally
20 have information on how effective training programs
21 are, but I would be really interested in hearing that
22 as well.

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1 UNIDENTIFIED SPEAKER: As a curmudgeon, I'd
2 like to take on my wine inebriated laboratorians and
3 actually select -- and I'm not sure it's reasonable to
4 say that manufacturers should select the most accurate
5 lots to go to the hospital and therefore lower the
6 overall accuracy for patients not going to the
7 hospital.

8 DR. BENSON: I don't think in any way we
9 would want that, either.

10 UNIDENTIFIED SPEAKER: No, but that's what
11 he was suggesting. He was suggesting that they could
12 stretch themselves, take their best lots which meant
13 12.5 percent, put those in the hospital, and leave the
14 rest for the patients not going to the hospital.

15 DR. HARPER: Well, they were discussing
16 hospital, but he didn't exclude lay users.

17 DR. BENSON: Right.

18 DR. HARPER: But I would like to point out
19 that this is definitely an issue that we've heard
20 about, that manufacturing criteria may vary quite
21 broadly between manufacturers, and sometimes it may be
22 that the criteria used sometimes is the ISO criteria

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1 itself. So it would be interesting to see what people
2 think would be reasonable acceptance criteria for
3 manufacturing lot release. Because that really has a
4 bit impact on performance in the field.

5 DR. KIECHLE: Fritz Kiechle from Florida. I
6 was a part of that conversation, and we did not
7 emphasize hospital use only. It was strictly a
8 guideline for everywhere.

9 I wanted to address the issue of training.
10 There have been some studies published, I believe from
11 the Cleveland Clinic, that illustrate very clearly
12 that if one chooses to place the trainee in front of a
13 videotape or CD or some other computerized learning
14 tool, that they will fail a recertification test much
15 more frequently than someone that actually has like 4
16 on 1 personalized training activity that lasts for at
17 least an hour. So you actually have to sort of see it
18 then do it and then teach it. The old rule still
19 works, and it works very well. It's then embroiled in
20 the brain and stays there.

21 And we have continued to hire people as
22 point of care coordinators to carry out this kind of

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1 retraining recertification program so we have enough
2 of them to actually do it one on one.

3 DR. WHITE: I'm Neil White from Washington
4 University in St. Louis. I just want to maybe be a
5 curmudgeon as well. I think we have to consider that
6 there may be two -- that we need to have two different
7 sets of standards. 12.5 percent may not be adequate
8 for safety in an ICU-type glycemic control setting.
9 That's not to say that we can't do better for the
10 patients in the field, but if getting to the standard
11 that needs to be used in an ICU setting produces a
12 product which for one reason or another, cost or size
13 or usability is not appropriate in the field, then we
14 may have to have two different sets of products and
15 two different sets of standards.

16 DR. HIRSCH: Okay, what we're going to do is
17 we're going to move on, since it doesn't appear we can
18 get this slide deck open. Our next speaker, Dr. Jim
19 Rollins from the Center of Medicare and Medicaid
20 Services in Baltimore, has agreed to give his
21 presentation without slides, which I think is quite
22 noble and brave. Dr. Rollins is going to talk about

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1 the payer perspective reimbursement issues associated
2 with glycemic control. And this talk is not being
3 sponsored by Microsoft, I take it. Dr. Rollins?

4 DR. ROLLINS: Thank you. Actually, I'm a
5 Mac man, but that's okay. Good morning. My name is
6 Jim Rollins, and I'm the Director of the Division of
7 Items and Services for Medicare. And I'm here today
8 to discuss Medicare's position on home glucose
9 monitoring.

10 Actually, I had a quote but you can't see.

11 But I'll read part of the quote for you.

12 This was a quote that was taken from a famous case in
13 Virginia, which describes the complexities of what we
14 have to deal with when considering coverage of items
15 and services. And the quote goes this way:

16 "There can be no doubt but that the statutes
17 and provisions in question involving the financing of
18 Medicare and Medicaid are among the most completely
19 impenetrable text within human experience." And I'll
20 stop at that. As I said, I don't have slides, but all
21 of this will be on slides, which we can make available
22 later.

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1 The Social Security Act, 1862 (a) (1) (A),
2 gives Medicare the authority to cover or noncover
3 items or services. But in order for items or services
4 to be covered, they must meet three criteria. Number
5 one, they must fall within at least one of the benefit
6 categories established by the Social Security Act;
7 number two, the item or service must not be
8 specifically excluded by the Act; and number three,
9 the item or service must be reasonable and necessary.

10 Let's look at some of the requirements for
11 coverage. First, the need for an item or service to
12 fall within at least one of the benefit categories.

13 The Social Security Act lists a number of
14 benefit categories. A few examples are: hospital
15 services, physician services or incident to, as well
16 as drugs and biologicals that are not self-
17 administered. When looking at home glucose monitors,
18 they fall within the Durable Medical Equipment benefit
19 category, also known as DME. DME characteristics
20 include, they can withstand repeated uses; they're
21 primarily and customarily used to serve a medical
22 purpose; they generally are not useful to a person in

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1 the absence or illness; and they are appropriate in
2 the patient's home.

3 Reasonable and necessary is another
4 requirement as stated in the Social Security Act. It
5 states, quote, "No payment may be made for items or
6 services which except for items and services described
7 in a succeeding subparagraph, are not reasonable or
8 necessary for the diagnosis or treatment of illness or
9 injury, or to improve the functioning of a malformed
10 body member." When determining if an item or service
11 is reasonable or necessary, Medicare must make sure
12 that patients within the Medicare population receive a
13 clinically meaningful benefit from that item or
14 service. Reasonable and necessary requires Medicare
15 to consider the following questions when evaluating an
16 item or service. Number one, does it improve health
17 outcomes from the Medicare population? Number two, is
18 it generalizable to the Medicare population? And
19 number three, is it generalizable to the general
20 provider community?

21 And let me make a quick aside. Medicare,
22 currently we have about 44 million beneficiaries.

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1 About 85 percent of those beneficiaries are 65 and
2 older. Fourteen percent get Medicare because they're
3 on disability, and then one percent for persons who
4 have in stage renal disease. So when we refer to
5 Medicare beneficiary and when we look at evidence
6 which supports the use in this particular population,
7 we basically look for evidence which supports based on
8 persons being 65 and older.

9 The next slide I was going to show you was
10 going to be a graphic presentation of the NCD process.
11 NCD is short for National Coverage of Determination.
12 And these are the measures that we put in place in
13 determining whether or not we're going to cover an
14 item or a service. National Coverage of
15 Determination, also known as NCDs, can be internally
16 or externally generated. We follow a timeline.
17 Normally the timeline is about nine months, but
18 sometimes it can be modified if there's going to be a
19 technology assessment or a MEDCAC review on the topic.
20 The Social Security Act states that there must be a
21 benefit category, and in performing an NCD we also
22 have to confirm that that particular item or service

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1 does fall under a particular benefit category. The
2 NCD process is evidence based. It's used to identify
3 peer-reviewed medical literature to determine the
4 effectiveness of an item or a service that is
5 requested. And after public comment, a final decision
6 memorandum is produced, stating either coverage or
7 noncoverage for that particular item or service.

8 The Code of Federal Regulation also
9 addresses items or services covered by Medicare. This
10 document specifically addresses the different
11 diagnostic tests performed on beneficiaries, the
12 provider who is treating the beneficiary for the
13 medical problem, and how the results of the test are
14 handled by the provider.

15 Now, we're going to look specifically at the
16 use of glucose monitoring in the Medicare population.
17 In 2009, Medicare spent almost \$2 billion on glucose
18 testing and supply. Almost 17 million claims were
19 generated. By comparison, during that same time
20 period, Medicare spent about \$2 billion on oxygen and
21 equipment, and almost \$1 billion on power mobility
22 devices.

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1 Now, we're going to take a look at the
2 history of coverage for glucose monitoring by
3 Medicare. There are two separate benefits for
4 Medicare that Medicare can use to cover home glucose
5 monitoring. One I mentioned earlier was the DME
6 benefit, and the second one is the diabetic supply
7 benefit. Prior to the Balanced Budget Act of 1997,
8 Medicare covered home glucose monitoring only for
9 insulin dependent diabetics. But after this Act was
10 initiated, it started supplying this benefit to non-
11 insulin dependent diabetics.

12 Earlier I talked about the NCD process.
13 There's a similar process that's known as LCD, which
14 is short for local coverage determination. And it
15 basically follows the same type of process in terms of
16 evaluating the medical literature to determine whether
17 or not a particular item or service is found to be
18 effective. CMS has both NCDs as well as LCDs, which
19 adjust the use of home glucose monitoring. In
20 general, the NCDs define the device that can be used
21 as well as the patient criteria; whereas, the LCDs
22 define accessories, supplies, as well as utilization

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1 of the device. When reviewing the NCD, it
2 specifically states patients' criteria, which are the
3 following. Number one, the patient must have a
4 diagnosis of diabetes. Number two, it includes the
5 requirement that the treating physician must state
6 that the patient or an authorized caregiver is capable
7 of being trained to use the device and monitor the
8 patient. And number three, the document designates
9 that the device is designed for home use rather than
10 for clinical use.

11 Also, because of visual impairment as a
12 potential complication of diabetes, Medicare also has
13 authorized the use of special devices for persons
14 suffering with this affliction. These devices are
15 reliable, accurate, and some devices also include
16 voice synthesizers as well as automatic timers. In
17 order for a patient to qualify for these special
18 devices, the treating physician must certify that the
19 beneficiary is visually impaired and its severity is
20 so that it requires the use of these special devices.

21 Now, let's take a look at the LCDs. As I
22 noted before, they generally define accessories as

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1 well as supplies as well as utilization use. LCD
2 qualification of supplies and accessories include the
3 following: that the patient must have a diagnosis of
4 diabetes; that the glucose monitor, accessories and
5 supplies must be ordered by the treating physician and
6 they must maintain records on that treatment; and
7 also, that there must be patient or caregiver training
8 on the device.

9 Other LCD requirements include the
10 maintenance of records of the glucose results and the
11 fact that the device is designed for home use only.
12 The LCD also gives guidance on utilization use. These
13 guidelines note that non-insulin dependent diabetics
14 can get up to

15 100 test strips and lancets every three
16 months, while insulin-dependent diabetics can get up
17 to 400 test strips and lancets every three months.
18 These guidelines also state that higher amounts are
19 available and are covered if justified by clinical
20 documentation which must be submitted by the provider.
21 LCDs also note requirement criteria for supplies as
22 well as accessories, and these include: that coverage

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1 criteria for glucose monitors must be met; that the
2 treating physician has seen the patient and addressed
3 diabetes care one year prior to dispensing the
4 supplies; that during the time of the visit there is
5 documentation of the type of therapy, and for those
6 who are treated with insulin, the number of daily
7 injections; and number four, that the beneficiary has
8 nearly exhausted the supply of items dispensed.

9 So in summary, let me conclude by saying,
10 number one, CMS does have the statutory authority to
11 cover home glucose monitoring devices, supplies and
12 accessories. Number two, CMS uses both the NCD
13 process as well as the LCD process to govern the use
14 of glucose monitoring. And number three, patients who
15 have insulin-dependent diabetes as well as non-insulin
16 dependent diabetes are eligible for glucose monitors
17 supplies as well as accessories. And that's it.

18 DR. HIRSCH: Yeah, we'll be able to make the
19 slides available. Yes, we'll be able to put them up
20 on the Web site.

21 DR. PINKOS: No, they should e-mail me. My
22 name's Arleene Pinkos, and my name appears in the

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1 Federal Register announcement. They won't go up on
2 the Web site.

3 DR. HIRSCH: Questions for Dr. Rollins? I'm
4 going to start. I am the medical director of a large
5 academic diabetes clinic at the University of
6 Washington in Seattle. And one of the things that is
7 exploding right now, and I'm not sure people
8 appreciate the fact that the number of people with
9 Type 1 diabetes in Medicare age over the age of 65 is
10 exploding. I don't know what the actual numbers are,
11 but as this population is living longer and doing
12 better, they are reaching Medicare age.

13 And I think that there are a lot of issues
14 with this that we are not prepared to deal with,
15 because up until now Type 1 diabetes has mostly been a
16 pediatric disease. Well, it's now become a geriatric
17 disease. And so, the question I have for you as you
18 were going through what Medicare covers in terms of
19 home blood glucose monitoring supplies -- as we have
20 these patients both on pumps and frequent, frequent
21 testing, we showed in a March ADRF trial as an example
22 that these patients are checking six, seven, eight

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1 times were day, and that's an average. And I guess
2 the issue is is that for these patients with Type 1
3 diabetes, three strips a day is never enough for this
4 population. And what it does is it just adds to the
5 more of the burden of documentation. And I'm
6 wondering if there are any plans for this older
7 population with Type 1 diabetes, if we can do
8 something to sort of ease this documentation burden
9 that we are all facing as these patients are
10 successfully entering the age of geriatrics?

11 DR. ROLLINS: I think that CMS would be
12 willing to consider modifying documentation. I think
13 that if you've got a patient who's using four, five,
14 six seven strips a day, does that mean that that
15 patient needs to have all of that documented on that
16 log? I think that there are things that can be put in
17 place that can address that. So I would say that I
18 think that CMS can yes, can accommodate this.

19 DR. HIRSCH: Okay. And I will just say what
20 we do, which I've never seen CMS or anybody really
21 talk about, is using electronic medical records and
22 electronic downloadings of the meters making this very

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1 simple. It does simplify it, and I just put a plead
2 out to clinicians and CMS and also the industry about
3 pushing the technology -- actually very old technology
4 that can make this documentation much easier than I
5 think most people have to struggle with now.

6 DR. ROLLINS: I think electronic downloads
7 is an excellent example of a new technology which CMS
8 as well as I'm pretty sure a lot of other commercial
9 insurers are willing to embrace. As long as there's
10 documentation -- and as I say I can't speak for other
11 companies and I can't say that currently we have
12 things set up that way. But I do think as I say,
13 electronic documentation an downloading of those
14 results to show that those activities did take place,
15 is something that we would encourage.

16 DR. HIRSCH: Great. Claudia?

17 DR. GRAHAM: Yes, Claudia Graham with DexCom
18 from San Diego, California. Could you comment on the
19 in-patient tight glycemic control with regards to
20 Medicare payment, DRGs, compensation back to the
21 hospital. I think there's some confusion perhaps
22 existing, and where Medicare may be going with regard

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1 to in-patient payment?

2 DR. ROLLINS: I really cannot address that.

3 All I can say basically is I would make the assumption
4 that reimbursement would be a part of the DRG. That's
5 all I can say.

6 DR. HIRSCH: David?

7 DR. KLONOFF: David Klonoff, Mills Peninsula
8 Health Services, San Mateo. You mentioned that
9 training is needed to receive coverage. What type of
10 training for blood glucose monitoring are you
11 referring to? Is it class or learning from the doc ?
12 would this be enrolling in a class or working with a
13 doctor or an educator?

14 DR. ROLLINS: I think working with a doctor,
15 or working with an educator. And I think that a lot
16 of physician offices may be associated with a diabetic
17 educator or something on that order. That would be
18 sufficient in terms of documenting that the patient or
19 the caregiver has been trained on using that
20 particular device.

21 DR. KLONOFF: Are you requiring that
22 documentation currently?

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1 DR. ROLLINS: We do require documetnatio
2 that the patient or the caregiver has been shown ? and
3 are proficient in using the device.

4 DR. KLONOFF: Thank you.

5 DR. CASABURI: Good morning. Two questions
6 to the Panel. I'm Dan Casaaburi from Sanofi-aventis.
7 And the first question I have is, does Medicare have a
8 policy on reimbursement for continuous glucose
9 monitoring systems at this time? And then secondly, a
10 question to the Panel with regard to the use of
11 continuous glucose monitoring systems, not necessarily
12 to drive insulin dosage, but perhaps has an alarm
13 system for hypoglycemia. And that is somewhat of an
14 off-label use in the Type 1 pediatric population at
15 this time.

16 DR. ROLLINS: Actually, I can answer the --
17 let me try the first one first. Actually, somebody in
18 the audience I think might be able to answer both of
19 those questions. It just so happens that one of my
20 colleagues is here. And she was the one who was
21 actually responsible for one of the MEDCACs that we
22 had specifically addressing the use of glucose

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1 monitoring devices., Dr. Beth Koller. I think she can
2 answer both of those questions.

3 DR. CASABURI: Okay, first question is that
4 the Medicare's position with regard to reimbursement
5 on continuous glucose monitoring systems. And then
6 the second one is more of a general regulatory
7 question or medical question.

8 DR. KOLLER: I'll do one at a time.

9 DR. CASABURI: Well, about -- go ahead.

10 DR. KOLLER: Okay. As Dr. Rollins
11 indicated, Medicare makes its decisions and implements
12 its decisions at two levels. The first is at a
13 national level. And that's a decision that is made.
14 Once that decision is made it applies uniformly across
15 the country. Whereas -- most people are not really
16 familiar with this, but many decisions for Medicare
17 are made at the level of the local contractors. And
18 this is just a reflection of the historical
19 development of the Medicare program in which
20 centralization -- there were concerns about
21 centralization of medical care delivery and decision-
22 making.

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1 And at this time, decisions on continuous
2 glucose monitors are made at the level of the local
3 contractors. But the local contractors have
4 significant amount of experience in terms of
5 understanding glucose monitoring and our patient
6 population. We also have another decision in place
7 which has some bearing on this. We do cover and have
8 a national decision for insulin pumps. And insulin
9 pumps can be provided to only a limited number of
10 patients who fit certain criteria. They have to
11 demonstrate additional need in terms of problems in
12 terms of maintaining glycemic control -- having
13 problems with excess, hypoglycemia, et cetera.

14 And so in general, the contract medical
15 directors, the local contractors, have provided
16 continuous glucose monitoring only to that subset who
17 are on pumps. They may choose to also provide
18 continuous glucose monitoring for a shorter interval -
19 - for example, a short stay, 72 hours, et cetera, so
20 that someone can obtain information so that they can
21 guide their therapies, that they can investigate
22 nocturnal hypoglycemia, et cetera. But that decision

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1 is not at a national level; it's a level of the local
2 contractor. So you have to justify it. One of the
3 other things --

4 DR. HIRSCH: Dr. Koller, we are about out of
5 time. If you want to do the second question very
6 quickly.

7 DR. HARPER: I can answer the second
8 question.

9 DR. CASABURI: Okay, go ahead. Thank you.

10 DR. HARPER: So currently, continuous
11 glucose monitors are only actually approved for
12 tracking and trending. So they aren't approved for
13 any sort of a replacement of the functions of glucose
14 meters. However, the encouraging part is, it's part of
15 the development of an artificial pancreas. There are
16 investigators who are actually looking into doing
17 studies, and then there are some that are well on the
18 way of performing studies to evaluate the performance
19 of CGMs to see whether or not they could be effective
20 in alerting patients who might be hypoglycemic --
21 especially at night, they're starting at night. So we
22 are encouraged by that.

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1 DR. HIRSCH: Dr. Pinkos? Arleen?

2 DR. CASABURI: I just wanted to invite Dr.
3 Hirsch to comment on that, with his extensive
4 experience in Type 1s and pediatrics, the use of
5 glucose monitor -- continuous glucose monitoring.

6 DR. HIRSCH: My bottom line is, we are not
7 quite there yet. We're getting closer. I'm very
8 excited about the future, but right now as we sit here
9 in 2010 we're not quite ready yet to do that.

10 DR. PINKOS: Just a quick question. Pinkos,
11 FDA. As much of technology is driven by
12 reimbursement, is there any potential for higher
13 reimbursement for more accurate point of care meters,
14 and if so, what would have to be done to support that?

15 DR. ROLLINS: Actually, the area that I'm
16 responsible for, coverage analysis group, we have
17 nothing to do with reimbursement. That actually falls
18 under a different part of CMS called CMM. So in terms
19 of reimbursement, I really could not address that.

20 DR. HIRSCH: Okay. Thank you all very much.
21 It is now time for our break at the Grand Foyer. We
22 will meet back here at exactly 11 o'clock for our next

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1 discussion.

2 (Pause.)

3 DR. HIRSCH: Okay, if everybody can have a
4 seat, we're about to get started. And while you're
5 finding your seat, I'm going to make an announcement
6 here, that we would encourage those of you who are
7 actually in the trenches seeing patients in the
8 hospital, specifically in the ICUs, to feel free to
9 come up and comment on some of these issues that we
10 are discussing this morning.

11 Our next talk is going to be by Dr. Rich
12 Bergenstal, who is the Executive Director at the
13 International Diabetes Center outside of Minneapolis.
14 Rich is a good friend of mine for many years, who also
15 right now is President of Science and Medicine for the
16 American Diabetes Association. And Rich is going to
17 talk to us about Advantages of Tight Glycemic Control
18 in the Hospital Setting.

19 DR. BERGENSTAL: Thank you very much, Irl
20 and thank you, Courtney and Arleene and others for the
21 invitation to have an opportunity to join in this
22 dialogue today. I will give you my conflicts. My

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1 Center in Minneapolis does lots of clinical trials on
2 almost all new devices and drugs, but no personal
3 compensation is received for any of these. And at the
4 bottom bullet there, I am an officer, volunteer role
5 for the ADA. And as I start off this discussion,
6 which obviously is going to be focused on the
7 hospital, let me start with a few points on the
8 American Diabetes Association and then end with a few
9 points relevant to our discussion I think.

10 And to yesterday, for those of you who were
11 here, you remember yesterday there was some discussion
12 of how tight is tight enough for the standards? And
13 the American Diabetes Association held a conference
14 back in 1986 that said, when the current total error
15 was around 15 percent, the American Diabetes
16 Association said, well, why shouldn't it be tighter --
17 always the patient advocate, can we do better -- and
18 said 10 percent. And yet, when they held their next
19 conference in 1993, they realized we really weren't
20 meeting that 10 percent. And yet to the surprise of
21 some, they said, well, let's make it 5 percent.

22 But let me put the context to that, because

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1 it got brought up a few times yesterday. In June of
2 '93, for those of you who remember, that's when the
3 DCCT results came out and said, dramatic improvements
4 in eye, kidney and nerve disease when you improve the
5 hemoglobin A1C, but there was a significant increase
6 in hypoglycemia. And so in light of that notion that
7 we really need to avoid this hypoglycemia but we
8 really want tight control, that was some of the
9 context around saying, let's try to make the meters as
10 accurate as possible.

11 If we now put it into to today's perspective
12 in learning what we have, I think that the American
13 Diabetes Association would say that -- and I think the
14 tenor of yesterday's meeting, that glucose monitoring
15 is clearly one important component in safely achieving
16 improved glycemic control -- there didn't seem to be
17 any argument in that yesterday. And that even going
18 to the point of non-insulin users, the IDF recently ?
19 many of you in the room were part of a panel that
20 said, if you actually record the purpose of the
21 testing for non- insulin users and instruct them on
22 how to use the data, it can be helpful. And you may

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1 have seen last, couple weeks ago even the National
2 Health Service in England - - not always the most
3 generous in their supplies ? has said that even the
4 non-insulin users, if there is a plan for how to use
5 the data and some documentations of this plan, that it
6 makes some sense. So I think following on the theme
7 of the last discussion of having in the record that
8 you are actually using the data, it can be helpful.

9 So we're really not achieving our goals
10 overall very well yet. And yesterday it came up
11 again, well, hypoglycemia seems to be a major factor.
12 How much of this is meter-related versus other
13 factors? And I will just share with you a little bit
14 of data from the Accord trial that said, what we
15 documented was that the biggest factor was actually
16 not carb counting actually or changing meals. Nowhere
17 on the Top Ten list was meter inaccuracy, but then I
18 don't think it was really looked for carefully. Did
19 we ask our patients, did we test their meters? So
20 clearly it may be a factor, but we have many other
21 factors that clearly need to be overcome to improve
22 control. So maybe we're using the A1C too much and

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1 not using SMBG in concert enough with it to make our
2 adjustments, and that would be my plea.

3 So I think that there is room for improved
4 accuracy in the hospital, and that's what we'll talk
5 about. I think the outpatient, there's room for
6 improvement, but it really seems that it has to start
7 in the hospital, but equally should be the efforts on
8 how to use the data. I think that probably deserves
9 equal attention to the improved accuracy. And again,
10 as has been mentioned, continuous glucose monitoring
11 holds great potential with further study and
12 innovation.

13 So thanks to some of my colleagues -- some
14 are in the room -- and for sharing some data and some
15 slides for me -- here's the problem in the hospital
16 setting, that people with diabetes or abnormal
17 glucoses that you might call pre-diabetes, make up a
18 huge number of patients in the hospital now ? some 12
19 to 25 percent. In our hospital it's 20 percent at any
20 given time. And in the cardiac surgery patients, it's
21 up to 50 percent of them if you actually test them,
22 have diabetes or impaired glucose tolerant. So we do

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1 need to figure this out and have a good plan of
2 action. It used to be that we didn't worry too much
3 about hyperglycemia and sliding scales, as Dr. Hirsch
4 said was the standard of the day. That is changing,
5 and we are understanding the forces that are leading
6 to high blood sugars and the forces that are leading
7 to low blood sugars. And each of these need their
8 attention if we're go end up in the middle spot of
9 good control without adverse effects.

10 So thanks to Dr. Furnary, who I believe is
11 still here today, he started tracking some of the deep
12 sternal wound infections and showing they were
13 actually much higher in people with diabetes. And
14 this seemed rather obvious and important. And then
15 when he developed the Portland Protocol of which many
16 of the protocols today are derivatives thereof,
17 started to see these sternal wound infections get less
18 and less. So I think this is one of those facts
19 that's really hard to argue with to say, improved
20 control had a major impact. Then there was the study
21 that we have all heard about and quoted. And whether
22 you call it the Leuven Study or -- the Van den Berghe

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1 Study, really, is how it's usually talked about --
2 started changing practice. And because a blood sugar
3 103 versus 153 in that Center with very precise
4 monitoring led to dramatic decreases in mortality,
5 whether you looked at it, mortality getting out of the
6 ICU or survival for the entire hospital stay or
7 transfusions or sepsis or renal insufficiency, several
8 parameters.

9 So this started to change things and make
10 people start to think about the level of control.
11 Then other data was collected along the way, too, to
12 say that, this seems to be on a population level. The
13 higher the glucoses, the higher the mortality rates.
14 And then back to Dr. Furnary again, the higher the
15 glucoses on average, the higher the mortality rates in
16 post cabbage patients -- even to the point that a
17 blood sugar of 200 in the first post-op sugar could
18 have a seven-fold impact on risk of increasing
19 mortality. So these were the factors that started
20 people thinking that improved glucose control, maybe
21 even very tight glucose control, was critical in the
22 hospital setting.

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1 Then as always happens, there comes a series
2 of data to say, as we look at different patient
3 populations, wait a minute, we're not consistently
4 finding this, that patients in sepsis treated to tight
5 control. And again, the numbers are fairly similar
6 there -- 112 versus 151 -- no difference in mortality.
7 It didn't harm you to get that tight in terms of
8 mortality, but there was more hypoglycemia. And then
9 meta-analysis were starting to be done to say, wait,
10 are we ready for everyone to be at a blood sugar of
11 100? There really was no change in overall mortality
12 when you put all the studies together, but there was
13 some increase in hypoglycemia. So how tight is tight
14 enough? American Diabetes Association and Association
15 of Clinical Endocrinologists got together and said,
16 well, let's work on this. And they were working on
17 this and putting all of these data that I just showed
18 you and several others in context. And as they were
19 deliberating, another study came out that we've
20 referred to yesterday several times, but I'll just
21 briefly mention again -- the NICE-SUGAR study.

22 So this working group was meeting, and then

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1 these results were released. And so it obviously had
2 a significant influence on their deliberations because
3 this was the largest trial ? 6,000 patients ? who were
4 now randomized to tight control, or I won't say usual
5 control, I'll say good control -- so good control
6 versus very good control in 40 centers using somewhat
7 standard approach. Although, as we heard yesterday,
8 standard meaning targets but not necessarily how the
9 glucose was measured in all sites and was hard to
10 determine arterial venous capillary. But they did get
11 a separation of glucose control over time, and yet
12 that separation, the lower, tighter control over time
13 actually led to a slightly increased mortality, a 14
14 percent increase, or a 2.6 percent absolute increase.
15 And there was more hypoglycemia, as we at the bottom
16 line there, had talked about yesterday -- some 13 to
17 14-fold increase. And there's the 90-day mortality
18 data highlighted in the middle.

19 So with this, the discussion said, well, the
20 standard group of 140 to 180 had reasonable outcomes ?
21 still what we would consider good control. The group
22 going from 80 to 110 had no significant benefit over

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1 that group. So that maybe the new standard should be
2 closer to what we would say, good control in this 140
3 to 180 range, although not tested was obviously that
4 in-between group of, how about 110 to 140. And when
5 you look at another nice paper in circulation in 2008
6 that sort of plots the in-hospital mortality after
7 acute MIs, you can see that the lowest point seems to
8 be somewhere down around that 110 mark and goes up on
9 both sides of that, so that if it were possible to get
10 there safely and not overshoot, that somewhere around
11 that 110 to 140 would be a reasonable goal if we can
12 find a way to get there safely, whether that's better
13 protocols, more accurate measurement, better training
14 - - all of the factors that go into actually achieving
15 this safely.

16 So the conclusions of the working group
17 making a joint statement was that good control is
18 important; that near normal control, we're not there
19 quite yet; that by no means should we go back to the
20 laissez-faire days of over 180; that 140 to 180 makes
21 sense but probably 110 to 140 in hospitals and
22 settings that can do it safely and have shown that is

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1 reasonable, but again deserves to be tested; and
2 finally, avoiding hypoglycemia is critical. I think
3 I'll skip the outpatient, because I have a feeling Dr.
4 Hirsch will be talking about it. But I'll just
5 mention that IV protocols are critically important
6 that they're used effectively and people are trained.
7 You can get good results when they are implemented in
8 a systematic way. There's lots of criteria to say what
9 makes a really good protocol and it really has to do
10 mostly with training of the staff to implement them
11 carefully.

12 In the non-ICU setting, I think it's equally
13 important to understand the physiology of insulin and
14 to have orders that utilize the principles ? I'm going
15 to go straight to this of ? I like my friend, Dr.

16 Inzuci's BBC for those of you who listen to
17 the radio ? the basal, bolus and correction. IN our
18 hospital we call it a complete insulin order. We try
19 to enforce, do not take off an insulin order that does
20 not have three parts to it written: a background
21 insulin, a mealtime, standard dose and a small
22 correction factor. That I think is how to do it safely

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1 in the non-ICU setting. Avoiding hypoglycemia, we are
2 learning, seems to be a critical factor. And we come
3 down to whether the meter's at 20 percent and 15
4 milligrams per deciliter are adequate in the hospital.
5 I would say it's appropriate to be looking at tighter
6 standards in the hospital as the first goal to
7 minimize this risk of hypoglycemia and allow people
8 the confidence to continue to improve control.

9 And finally, let's look at whether there's
10 anything new coming. I'll show you one bit of data,
11 because it came up yesterday several times. There's
12 one continuous glucose monitoring system that was
13 presented last week in Europe, not approved in the
14 U.S. But just to show you that continually monitoring
15 intravenous blood sugars can get MARDs or MAREs around
16 six percent, and almost all of the values in the A-B
17 zone. And this was the first 19 patients actually
18 done in the hospital setting. And you can see pretty
19 reasonable values, but I think what's even more
20 important is this continuous printout. Imagine this
21 now, if this were implemented, that you actually could
22 see, have confidence in the values and be able to

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1 detect a low one, that you can't do even doing every
2 two-hour blood sugars or every four-hour YSIs as was
3 done here.

4 So this technology, if continued to be
5 proven safe and accurate, I think holds a great
6 promise to say, can we get closer to that 100 to 140
7 or near normal and avoid hypoglycemia. Then we may be
8 able to really prove the true value of near normal
9 blood sugars, which we're having difficulty at the
10 moment safely achieving.

11 So final bit of advice in conclusion for
12 this Panel is that I think the FDA ISO, the CLIA-POC,
13 which we talked about all three of these yesterday
14 quite a bit, are doing really important work to gather
15 this data and to write standards and guidelines. But
16 people with diabetes and practitioners don't always
17 look to ISO or CLIA for their main information.
18 They're looking to other organizations like the ADA
19 Diabetes Forecast or the standards of care that come
20 out every year. So that this partnering with these
21 agencies and professional organizations I think is
22 going to be the key if we're really going to change

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1 practice and get people using the devices the way
2 they're supposed to be used to improve control and get
3 us to the point where we need to be. So thank you,
4 and maybe we have time for a question.

5 DR. HIRSCH: Dr. Hellman, you go first.

6 DR. HELLMAN: Richard, again, thank you for
7 your comments. As one of the people who was part of
8 the Panel, along with Irl and many other people, one
9 of our great concerns we had was the issue of the
10 accuracy of the glucose meters. Because there are
11 critical situations in the hospitals.

12 But one of the things that resulted I think
13 in part from that, was there was a letter to the FDA
14 written by one of the past presidents of ACE and
15 signed by the President and another, asking
16 specifically for a 10 percent accuracy threshold. And
17 one of the things that is a concern and I wanted to
18 ask you, is has the American Diabetes Association
19 specifically considered a similar type of request?
20 Because one of the things that I have a problem with -
21 - there's no question that the hospital needs this
22 accuracy -- but I don't know how to define the people

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1 who are at great risk. Should we be telling people,
2 these meters that you have are good, but please don't
3 drive a commercial vehicle or go up a high ladder
4 because they're not really as accurate as they should
5 be for you in that setting when it's critical to know
6 that? It seems more reasonable to have an across-the-
7 board recommendation as a first effort, even if
8 technically you have different devices for the
9 hospitals. Has the ADA considered the position like
10 that? Because I would encourage it.

11 DR. BERGENSTAL: Well, I think the ADA is
12 thinking about this and is very interested in the
13 output of this meeting to maybe it's time to convene
14 another panel. Having been from 86 to 93, it's
15 probably time to have this discussion again. Because
16 I think it's ADA and ACE and others getting together
17 who are going to do the translation of this sort of
18 work into practice. So it may be time to seriously
19 consider that.

20 DR. HELLMAN: Thank you for letting me put
21 you on the spot.

22 DR. HIRSCH: Dr. Furnary? Richard?

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1 DR. FURNARY: That was a very nice talk.
2 Thanks very much. And I think it's important. The
3 topic of your talk is advantages of tight glycemc
4 control. I think it's important that the FDA hear --
5 and that's Courtney and Carol and everyone else --
6 hear what these real human advantages are, because
7 yesterday, Courtney presented and Carol presented
8 today, the disadvantages of hypoglycemia. And we
9 heard that there were 100 deaths that occurred between
10 1992 and 2009. And that's terrible. I hate that.
11 But even worse are the deaths that have occurred from
12 hyperglycemia in the same period. Now, if we just
13 look at the cardiac surgery database -- I'm probably
14 the only cardiac surgeon in the room silly enough to
15 be here -- between 2000 and 2009, the Society of
16 Thoracic Surgeons database. For patients with
17 diabetes, the mortality rate in this country was 3.6
18 percent. That's about 6 million patients.

19 At the same time, in Portland, our mortality
20 in the same years was 0.9 percent -- one-quarter of
21 the national mortality. Now, it's either I'm the best
22 surgeon in the world and my partners, which I don't

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1 believe, or the fact that we keep our patients at 7110
2 made a difference. And if you calculate the number of
3 deaths in those 6 million patients over 10 years. If
4 you take down the 2.7 percent, there are over 150,000
5 people in 10 years who would have suffered because of
6 hyperglycemia -- 2.7 percent of 6 million. That's a
7 huge number, and it's much bigger than 100 patients.

8 We can't lose sight of that. In Portland,
9 one out of 11 patients with diabetes dies after open-
10 heart surgery. In the rest of the country, it's about
11 one out of 28. That's a huge difference. And we did
12 this entire thing, Courtney and Carol and everybody
13 and Arleene at the FDA, with current hand-held meters,
14 with a 20 percent error. We didn't kill anyone from
15 hypoglycemia. I think it's fantastic that we should
16 get better and more accurate meters, but it's not just
17 the meter. You can't put the entire weight of TGC on
18 a meter, because the protocol matters. One of the
19 biggest differences as Dieter will probably talk
20 about, is it's the protocol that matters, and how
21 frequently you measure and how long they're
22 hypoglycemic.

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1 In our patient population, less than 5
2 percent of patients at 7110 go below 60, and the
3 average time below 60 before they get above 70 is 33
4 minutes. That's why there's no consequences of
5 hypoglycemia. Yes, it's better to have a good meter,
6 but it's even better to have a good protocol. I know
7 you can't regulate a protocol, but you can't put the
8 weight of the entire TGC onto the meter. And I think
9 it's a very important thing for everyone to hear.

10 DR. HIRSCH: Thank you, Tony. Very much
11 appreciate your comments, but we need to move on.
12 Rich, thank you very much. Our next speaker is going
13 to talk about why tight glycemia control may not be
14 appropriate in hospital settings, by Dieter Mesotten,
15 who's an anesthetist and intensivist at the University
16 Hospitals in Lueven. And when we met this morning, I
17 said, so you are a colleague of Dr. Van den Berghe?
18 He says, no, I'm a disciple. And so that's the
19 difference. We look very much forward to your
20 comments.

21 DR. MESOTTEN: Thanks a lot for the nice
22 introduction. First, I would like to thank the FDA

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1 for giving me the opportunity to talk about why tight
2 glycemic control may not be appropriate in hospital
3 settings. And that's a big like asking Bill Gates to
4 promote upcoming iPod from Microsoft.

5 So my talk will revolve around two main
6 issues: first of all, about the clinical validity of
7 tight glycemic control, and secondly about methodology
8 to do tight glycemic control. And we all know from
9 association studies that there's a J shape
10 relationship between risk of mortality and blood
11 glucose levels. So the lowest risk of dying you have
12 when you're on admission blood glucose levels, or your
13 mean levels across your ISU state are within the
14 normal range. And for adults this means 82, about
15 120, 130. So as soon as blood glucose levels go up,
16 you have an increased risk of dying in the ICU. And
17 the same accounts for the hypoglycemic range.

18 So association studies cannot delineate
19 whether hyperglycemia is adaptive. Maybe it's a good
20 thing and it's part of the survival response, or maybe
21 it has nothing to do with the risk of mortality; it's
22 just an innocent bystander. It may also be an

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1 actively contributing factor to adverse outcome. And
2 to test this hypothesis, back in '99, we started our
3 first study. And that hypothesis was to test whether
4 hypoglycemia was not an adaptive response.

5 In the first study we tested the do not
6 touch strategy, so the comparator, which will be
7 represented by the red lines throughout my talk,
8 versus a strict normal glycemc intervention group.
9 And this study was done in a surgical ICU. In this
10 study, 1,548 patients were randomized over 12 months'
11 period of time. Once again, tight glycemc control in
12 French group, maintained blood glucose levels, keeping
13 between 80 and 110 milligrams per deciliter. The
14 conventional group here on the insulization was
15 started, as soon as blood glucose level exceeded the
16 limit of 215 milligrams per deciliter, during that
17 threshold, above which you would get fluid shifts and
18 hypertension. It's very important that the
19 insulization was stopped as soon as blood glucose
20 levels went below 180 milligrams per deciliter.

21 And we all know from this study that tight
22 glycemc control reduced ICU mortality from 8 to 4.6

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1 percent. But there was a price for it.
2 Hyperglycemia, defined as blood glucose levels less
3 than 40 milligrams per deciliter, went up from 0.8 to
4 5.1 percent. And if you put this graphically, you can
5 clearly see that this survival benefit was maintained
6 throughout the entire hospital setting, from the ICU
7 as well as in the hospital. And even more, the
8 benefits of tight glyceic control were much more
9 pronounced in the patients that would stay in the ICU
10 for more than three days -- the so-called long-stay
11 ICU patients. And here, you had an absolute risk
12 reduction of about 8 percent.

13 As a first step to test generalizability --
14 and we've been talking about it several times -- we
15 took the same protocol, the same experiment, to our
16 medical ICU, which is right across the corridor in a
17 hospital. And this study was powered to detect a 4
18 percent absolute risk reduction in the long-stay ICU
19 patients -- so patients with an expected stay in the
20 ICU for more than three days. In this study, a total
21 of 1,200 patients were randomized, leaving us with 767
22 long-stay ICU patients over three-year periods of

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1 time. Once again, I would like to emphasize it had the
2 same design. In this study, we saw that intention to
3 treat population, so the 1,200 patients that tight
4 glycemic control, non-significantly reduced ICU
5 mortality from about 27 to 24 percent -- absolute risk
6 reduction of about 3 percent. However, for the long-
7 stay patient population, so the target group in this
8 study, it's decreased ICU mortality from 38 to 31
9 percent -- and here, with even a bigger increase in
10 hypoglycemia. It went from 3 to about 19 percent,
11 which is really high.

12 I said before, the medical ICU study was not
13 powered to detect a mortality difference in intention
14 to treat population. Therefore, we combined two study
15 populations in the mixed ICU population. So we had
16 2,748 patients. And on the left-hand panel you can
17 clearly appreciate that tight glycemic controlled
18 decreased the mortality risk from 24 to 20 percent.
19 And looking at long-stay ICU patients, it went from 38
20 to 30 percent. So we're talking about for the overall
21 population, 4 percent absolute risk reduction, and for
22 the prolonged ICU patient population, a decrease of 8

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1 percent.

2 As a final step, we took it to our pediatric
3 ICU population. And here, we had even a more tighter
4 blood glucose control. In infants, which meant
5 pediatric patients less than one years of age, we were
6 targeting 50 to 80 milligrams per deciliter. Children
7 defined as the age between 1 and 16 years old, was our
8 target range, 70 to 100 milligrams per deciliter.
9 Once again, our comparative was a strictly do not
10 touch strategy. Here in translation was also only
11 started when blood glucose levels exceed 215
12 milligrams per deciliter. And different to the other
13 studies, the primary ambient was length of stay. And
14 a study was powered to detect the difference in
15 inflammation measured by C-reactive protein, as
16 baseline risk of dying in the pediatric ICU is only 5
17 percent and it's really hard to show a much harder
18 difference.

19 In total we recruited seven patients, mostly
20 after cardiac surgery. And to a great surprise, even
21 in this population, we saw significantly mortality
22 reduction in our pediatric population. It went down

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1 from 5.7 percent to 2.6 percent; once again, an
2 absolute risk reduction of 3.1 percent, consistent
3 over the three trials. And here, hypoglycemia defined
4 as blood glucose levels less than 14 milligrams per
5 deciliter, went up from 1 to 25 percent. However,
6 needless to say, it was not unexpected, because we
7 were targeting in our neonates levels of 50 to 80
8 milligrams per deciliter, which is really close to the
9 threshold for hypoglycemia.

10 So I think it's fair to conclude that from
11 our Leuven studies that compared to the do not touch
12 strategy, achieving tight glyceimic control improves
13 the outcome of ICU patients, measured by maturity but
14 also measured by morbidity; for example, intervention
15 and perfection, less transfusions, less need for
16 prolonged ventilation and a decrease in critical
17 illness polyneuropathy. And these findings were
18 further corroborated by our mechanistical studies.
19 Tight glyceimic control improved mitochondrial
20 function, it improved the kidney, cardiac function.
21 It also reduced a material activation and it improved
22 leukocyte function and reduce inflammation.

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1 But I do have to warn you, there is a
2 specific setting in which these studies were done.
3 First of all, we're talking about three independent
4 single center trials, with a high study inclusion
5 rate; 95 percent in surgical ICU, 60 in the medical
6 and 68 in the pediatric ICU. We had a very passionate
7 PI, Professor (inaudible), and a nursing staff that
8 were fully dedicated to tight glycemic control. I
9 also have to mention that most blood glucose
10 measurements were done thorough arterial sampling.
11 Blood glucose analyzer was the only device in the
12 surgical and pediatric study, and the medical ICU, the
13 only device that was used was the HEMAQ. Insulin
14 infusion was only done through a central line and
15 using a very accurate syringe pump system. So this is
16 talking about a center with experience, passion and
17 adequate technology. And you can summarize in one
18 word, standardization in a proven concept design.

19 We all know about the enthusiasm and the
20 raving about these studies and implementation in
21 different protocols across the world. And many people
22 try to do follow-up studies to confirm our data in

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1 Leuven, whether from multi centers, single center
2 studies, five-step glucose control, Arabi, De La Rosa
3 and many others. However, the results are rather
4 disappointing. And I think there was some major
5 flaws. First of all, the multi center trials had to be
6 stopped due to increase in hypoglycemia, which was not
7 unexpected if you had read the Leuven studies. There
8 was also an inadequate separation of the glycemic
9 levels in both treatment groups. They could not reach
10 their targets. And these two factors caused that all
11 studies were under-powered to detect mortality
12 differences. So we cannot draw conclusions from these
13 studies.

14 And to address those statistical trial
15 design trial issues, the NICE-SUGAR trial was set up.
16 And once again -- we've talked about this many times -
17 - so this study randomized 6,104 patients that were
18 expected to require an ICU state of more than three
19 days, a bit like our medical ICU study. This study
20 was powered to detect a 3.8 absolute risk reduction in
21 a 90-day mortality, assuming a baseline risk mortality
22 of 30 percent. In the tight interventional group,

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1 they were looking at levels of 80 to 110. However,
2 the big difference is in the comparator. The
3 conventional group, here they were aiming for levels
4 between 180, and insulin infusions were stopped as
5 soon as they went below 144. And to everyone's great
6 surprise, even for the investigators in the NICE-SUGAR
7 trial, they saw an increase in mortality with tighter
8 glycemic control, absolute risk increase of 2.6
9 percent. So this study was really the mirror image of
10 the Leuven trials.

11 And now everyone is really puzzled and do
12 wonder, how could we possibly explain these different
13 outcomes? I would like to emphasize two things:

14 first, design and secondly, the intervention
15 itself. It's all clear to you that the Leuven studies
16 were done instead of a single set of trials, while
17 NICE-SUGAR was a very big 42 center multi center
18 trial. We all know that (inaudible) targets were both
19 the same, but there was already a big difference in
20 the control target. In Leuven we were aiming at 182
21 to 215, in NICE-SUGAR, 144 to 180. And what are the
22 implications for the study itself? If we're looking

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1 at the mean (inaudible) in the Leuven study, comparing
2 control convention group versus the tight glycemc
3 group, you see that there's a mean difference of about
4 50 milligrams per deciliter. And due to the design in
5 the NICE-SUGAR trial this was reduced to about 25
6 milligrams per deciliter, indicating a huge overlap in
7 the two study groups, which makes it really hard to
8 show a mortality difference.

9 So if you put this graphically, you can see
10 that the comparative group in red for the Leuven
11 compared to the one in white for the NICE-SUGAR trial,
12 went down our J-shaped curve. Does it have
13 statistical implications? Yes, it does. Because in
14 fact, NICE- SUGAR was looking at a one percent
15 absolute risk reduction, and such a study would have
16 required 70,000 patients. So there's some statistical
17 problems. But that's not the most important part.

18 I think further analysis is needed for the
19 intervention at the bedside. What were the nurses
20 doing? What were the doctors doing? And here,
21 there's a big difference. In Leuven we were working
22 with a very generic guideline. We want to stimulate

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1 intuitive decision making by the nurses. NICE-SUGAR,
2 we're using a strict if then algorithm with no freedom
3 for the nurses. Insulin in Leuven was only
4 administered as an infusion, using very accurate
5 syringe pumps. In NICE- SUGAR, the protocol allowed
6 infusions as well as both administration of insulin.
7 And all sort of pump were allowed for the metric,
8 syringe pumps, et cetera -- did not even record it.
9 And to build further on this meeting on blood glucose
10 meters, I would like to look further at the sampling
11 and with the course measurements.

12 In Leuven, we always tried to use arterial
13 blood. And we were measuring in the surgical and
14 pediatric study by a blood gas analyzer. In the NICE-
15 SUGAR trial, everything was allowed -- arterial,
16 capillary, venous, and they used diverse matters to
17 measure it. They did not even record it. They say,
18 with use of point of care glucose meters, our blood
19 gas analyzers are laboratory analyzed in routine use
20 at each hospital.

21 Does this affect results? And I think so.
22 And these are adopted from Duncan Young presented at

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1 the Brussels Intensive Care meeting last year. And
2 here we're looking at that, our duplicate measurements
3 from ICU patients. And we were looking at the 95
4 percent confidence level. The 95 confidence is
5 grossly the area between our limits of agreement, so
6 the 1.95 standard deviation on both sides, so the
7 mean. And we see that the most accurate one is a
8 blood gas analyzer, so got a 95 percent confidence
9 level of about 14 milligrams per deciliter. If you
10 compare to the gold standard, the laboratory, it goes
11 up to 21.6 milligrams per deciliter. If you look at
12 example at the HemoCue, which was used in a medical
13 study as well as in the Visup (ph) trial, it's about
14 the same, 20 milligrams per deciliter. But the worst
15 thing is that you're using capillary blood on strip
16 point of care blood glucose meters. Here, you've got
17 a 95 percent confidence interval of 37.8 milligrams
18 per deciliter. And even worse is mixing matters, which
19 happened in a NICE-SUGAR trial. One time you use a
20 blood gas analyzer, the other time the laboratory, and
21 the other time you use a point of care blood glucose
22 meter to steer your insulin infusion to get to tight

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1 glycemic control. Here, the 95 percent confidence
2 interval is 50.4 milligrams per deciliter. And this
3 should be seen in the background of your entire
4 glycemic control target range, which is only 30
5 milligrams per deciliter. So strip point of care and
6 mixed matters, they exceed this in limits.

7 So if you take a little closer look and
8 compare it with the center lab techniques, you see
9 that if you take the current ISO standards, allowing
10 20 percent error, a blood gas analyzer you've only 1
11 percent out of this 20 percent error range. If you
12 take arterial blood with a blood gas meter, you see
13 already 12 percent gets out of the range. And even
14 worse, and I think it's really unacceptable, when you
15 use capillary blood in a point of care blood glucose
16 meter, it goes up to 27 percent outside the target
17 range.

18 We did the study ourselves in the background
19 of an expert setting in tight glycemic control
20 management. And we compared two point of care meters
21 against the APL blood gas analyzer in 37 patients.
22 And you see for both point of care blood glucose

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1 meters, they all exceeded in the 95 percent confidence
2 interval, the target range for tight glycemic control.
3 For the AccuChek it was 40.5 milligrams per deciliter;
4 for the HemoCue, it was 37.1 milligrams per deciliter.
5 So your confidence interval for accuracy of your
6 measurement is bigger than your target range.

7 And our data were confirmed by a study in
8 the Netherlands, comparing blood glucose meters
9 against another blood gas analyzer, the rapid lab
10 blood gas analyzer by Siemens, using different
11 technology. And also there, you saw that the 95
12 confidence intervals greatly exceeded the target range
13 in tight glycemic control. For the AccuChek, this
14 Dutch study, it was 61.2 milligrams per deciliter, and
15 for the HemaCue it was 39.2 milligrams per deciliter.

16 How is this possible that these point of
17 care blood glucose meters are performing well in the
18 outpatient world and for ambulatory diabetics and not
19 in the ICU? And we've been talking about it a lot
20 yesterday, the interfering factors, such as
21 catecholamine therapy, adrenalin, no adrenaline,
22 anemia, which is prevalent in the ICU population --

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1 also drugs. Ascorbic acid is given intravenously in
2 the ICU patients, the confusion between capillary,
3 arterial blood. And I'm pretty sure there are many,
4 many unknown factors that interfere with this point of
5 care diagnostics.

6 I also would like to say that blood glucose
7 measurements do not stand on their own. And all
8 clinicians, among us they know. When you do give high
9 dose of insulin, you lower potassium levels. In
10 Leuven there's a standing order. You always measure
11 potassium levels when you do a blood glucose check.
12 And it's a standing order to maintain potassium levels
13 above 4 mEq/L. And you do it by supplementing it with
14 IV potassium. And it's clear from a pediatric study
15 that we had 6 percent more potassium levels below 4
16 mEq/L; however, without an increase in deep
17 hypocholelemia. But this with an expense of a 55
18 percent increase in participant supplements. So you
19 really need to check and do something about your
20 potassium levels when you're doing tight glycemc
21 control.

22 And I've heard in the audience that speakers

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1 are sometimes not really clear about their statements,
2 so I try to be very clear what I mean and when I
3 interpret this scientific data. For tight glycemc
4 control or any other narrow target range in the ICU,
5 capillary blood sampling is inadequate. And all point
6 of care blood glucose meters are inadequate. And they
7 do not belong in the ICU, and they should be banned.
8 And I think so far, only combined measurements of
9 arterial glucose and potassium in a blood gas analyzer
10 seem appropriate at the moment. What went wrong if
11 you're comparing the Leuven studies to the big multi-
12 center trials? Tight glycemc control and is
13 acknowledged by the scientific as well as the clinical
14 community, is a complex intervention. Proof of
15 concept studies, driven by a scientific question,
16 looking for efficacy in a strictly controlled setting
17 with high internal validity, were immediately
18 extrapolated to confirmation studies. But we're
19 looking at clinical practice, effectiveness,
20 pragmatism, and external validity of
21 generalizability. However, we underestimated the
22 giant step it was taking. We underestimated our

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1 technology.

2 And in summary, going back to my title,
3 tight glycemc control may not be appropriate in
4 hospital settings. I'm strongly against the current
5 methodology to do tight glycemc control, but I'm
6 strongly in favor of the scientific concept of tight
7 glycemc control. And with this important J-shaped
8 curve, I would like to say that I'm available for all
9 your questions. Thank you for your attention.

10 DR. IRL HIRSCH: Thank you for that
11 wonderful presentation. We're going to do this
12 quickly. Are there any burning questions, because we
13 are a few minutes already over time. Anybody want to
14 step up to the mike? Of course.

15 DR. FURNARY: So, just something to think
16 about over our lunch break -- my name's Tony Furnary.
17 I'm from Portland, Oregon. Just some things to think
18 about over the lunch break, and the things that I
19 think we can discuss in the Panel, is that although I
20 agree with your conclusion that tight glycemc control
21 can be done, I disagree that it cannot be done with
22 current devices. Although I agree that arterial is

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1 probably the best way to go, I disagree that it cannot
2 be done with other things, because we've done it for
3 18 years now, longer than has been done in Leuven.
4 And finally, I think the entire piece of NICE-SUGAR
5 goes away if someone actually reads the paper. And if
6 anyone -- how many people in this room have read the
7 paper? So 90 percent of all the deaths -- remember,
8 there's no difference of mortality in the hospital, no
9 difference of mortality 30 days. The difference in
10 mortality occurred at 90 days. And 90 percent of the
11 deaths in the study group and 91 percent of the deaths
12 in the control group were due to -- who can answer the
13 question besides Irl, because I told him?

14 (Hands raised.)

15 DR. FURNARY: DNR withdrawal of care. I
16 don't care how much glucose you give in the first
17 three, five, ten days, it's not going to affect the
18 family's decision to withdraw care 90 days later, end
19 of statement.

20 DR. HIRSCH: Last question.

21 DR. CEMBROWSKI: George Cembrowski,
22 University of Alberta. Our hospital participated in a

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1 nice study. While I run the laboratory, I really
2 didn't find out until the tail end. I was able to
3 data mine results that were done both on the same
4 patients within 15 minutes. Whole blood glucose is
5 done on a very popular care system, as well as
6 arterial blood glucose done on the radiometer. And
7 for a while, for at least three strip lots, the
8 manufacturer of this very popular system was biased
9 tied by at least one millimole or 15 or 20 percent,
10 which probably would have resulted in treatment of
11 artifactual hyperglycemia. The manufacturer
12 eventually got the act right, and this will be
13 published soon in Clinical Chemistry. So there are
14 more issues with NICE-SUGAR.

15 DR. MESOTTEN: I'm looking forward to the
16 data.

17 (Pause.)

18 DR. HIRSCH: I'm going to have you find my
19 talk, because I am the last talk before the lunch
20 break. Thank you. I have been asked to talk about
21 current practices and experience of tight glyceemic
22 control in the hospital settings. And I think another

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1 name for my talk could be The Reality Check.

2 What we are really addressing today is
3 current practices of insulin use in the hospital.
4 Please keep in mind, there was little interest in this
5 topic until the publication of the SICU data we just
6 heard about. And there's little teaching about insulin
7 and use for both inpatients and outpatients due to
8 lack of consensus on how to use insulin prior to the
9 era of insulin analogs. There have been minimal
10 randomized studies addressing best practices for
11 insulin use, particularly in non-research settings,
12 where systems are not ideal for insulin management.
13 And this is both on the inpatient and even on the
14 outpatient side.

15 With that in mind, how do we actually do?
16 Well, I would suggest that this is really an organized
17 chaos. Let me explain. This is one retrospective
18 look on how we do with over 2,900 patients with known
19 diabetes or diagnosed hyperglycemia during a three-
20 year review at a tertiary care hospital, an elderly
21 population, age of 69 years on average, length of
22 stay, almost six days. And what do we see? We see in

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1 the first 24 hours, 25 percent of patients had mean
2 glucose levels above 200 -- not TDC. What we see is
3 that for the entire hospitalization, 20 percent had
4 sustained hyperglycemia, mean hyperglycemia above 200.
5 And amazing to me, in the 24 hours before discharge,
6 21 percent, more than 1 in 5 with mean sustained
7 hyperglycemia greater than 200, with some with average
8 glucose levels above 300 in the 24 hours before
9 discharge. I don't think anybody in this room would
10 argue that this is too high.

11 As far as hypoglycemia is concerned, only
12 less than 1 percent of bedside measurements were less
13 than 60, and less than 0.2 percent of bedside
14 measurements were measured less than 40, with most of
15 us called now severe hypoglycemia. The point being,
16 we've heard a lot today about hypoglycemia, but at
17 least in this look-back, hypoglycemia was actually
18 quite rare.

19 Another study of 37 academic medical centers
20 in 2004 with 1,700 eligible adults with 79 percent
21 with known diagnoses of diabetes, over half on
22 outpatient insulin therapy, and at the time based on

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1 the Leuven study, the ICU target was less than 110
2 milligrams per deciliter. And taking a look back,
3 what was shown that almost a quarter were in the ICU
4 on day 1, 14 percent in the ICU on day 3. And what
5 you can see is looking at those within target, which
6 again was less than or equal to 110, it was quite
7 rare, either with diabetes or without diabetes, both
8 on days 2 and days 3. And what we see is percent of
9 ICU patients hyperglycemic. Now, here it is quite
10 common; whereas what we see here is on day 1, 2 and 3,
11 hyperglycemia is actually over 70, 80 percent with
12 SubQ insulin. IV insulin is better, but around half
13 of patients if not more than half of the patients on
14 each day, are hyperglycemic with glucose levels above
15 180.

16 So the blood sugar levels are not
17 controlled, no matter how they receive their insulin,
18 although IV did a bit better.

19 And then if we look at non-ICU patients,
20 they even did worse, whether on IV or SubQ. There was
21 only a statistical difference on day 2, as you can
22 see, but here we are talking about anywhere from 60 to

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1 even over 80 percent of patients with hyperglycemia in
2 the hospital in this very large study.

3 Other measures, severe hypoglycemia. In
4 this study, the find is less than 50 milligrams per
5 deciliter, less than 3 percent of all patients days.
6 A1C assessment for diabetic patients or less than 30
7 days prior than admission -- only about a third of
8 patients had their A1C no. Glucose measurements,
9 within eight hours of admission. And remember, over
10 half these patients were on insulin. Seventy-seven
11 percent of patients had their glucose levels measured,
12 meaning 23 percent of patients did not have a finger
13 stick glucose. And then as far as recommended
14 physiologic insulin therapy, which would either be
15 basal bolus therapy or IV therapy for those patients
16 NPO, it was a little under half for the whole
17 population, but a dramatic range based on the
18 hospital, anywhere from 12 to 77 percent. So huge
19 ranges.

20 So to summarize these data, persistent
21 hyperglycemia with rare hypoglycemia in this large
22 population. IV insulin was underutilized, and in fact

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1 less than half of ICU patients who were NPO received
2 IV insulin. And IV insulin was associated with
3 somewhat improved blood glucose control. There was a
4 wide variation in hospital performance of current
5 recommended diabetes care measures. And so the
6 question then comes, at least we don't order sliding
7 scale insulin in the hospital any longer. Right?
8 Wrong. We go back and look at the data, looking at a
9 review of insulin management in a large Boston
10 teaching hospital. Well, maybe this sliding scale
11 data is only valid in Boston. Let's take a look.

12 Forty-three percent of patients had basal
13 insulin ordered. Four percent of patients had
14 scheduled mealtime insulin -- four percent. Ninety
15 percent of patients in Boston received sliding scale
16 insulin; 47 percent with some basal insulin, 39
17 percent with oral hypoglycemic agents; and 23 percent
18 received sliding scale insulin only with no scheduled
19 insulin. Sliding scale insulin alone was associated
20 with a 20 milligram per deciliter risk of more
21 hyperglycemia.

22 So reviewing the literature, what is clear

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1 is that prior to NICE-SUGAR, the problem was not
2 hypoglycemia, but non-aggressive treatment of
3 hypoglycemia. Recommended targets have made for great
4 academic debates, but do not represent what's
5 happening out in the real world. The problem has
6 never been, we've been overaggressive with our insulin
7 protocols, as we are talking about this morning, but
8 rather as a medical community we've been nonchalant
9 with treating the severe hyperglycemia that is
10 pervasive in our hospitals.

11 Despite the fact we've been using insulin
12 for almost 90 years now, we don't use it intelligently
13 in the hospital. And is it even possible to improve
14 glucose control in the hospital? Well, there are many
15 possible strategies to have a successful glycemc
16 management program. Numerous IV and SubQ protocols
17 have been published with reasonable to good levels of
18 success. Rich showed some of those protocols. There
19 was no necessarily right way or wrong way to use
20 insulin in the hospital, if a protocol at that
21 hospital is shown to be efficacious and safe.
22 Example: What I want to show you now is a little bit

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1 of what we've done at the University of Washington
2 Medical Center over the last few years with our
3 inpatient diabetes therapy. Keys to success is
4 agreement between all clinicians and stakeholders to
5 glycemic targets and general philosophies of insulin
6 use. And I can't emphasize that enough -- education
7 with the staff, communication between the staff, and
8 examination for the staff for continued improvement --
9 a champion for each specialty to address questions and
10 concerns, very important -- and an appropriate culture
11 to prioritize and standardize glycemic control.

12 The culture of inpatient diabetes management
13 at the University of Washington, I feel is quite
14 important. Here is a picture of Seattle with some of
15 the other various landmarks. And here is the
16 University of Washington Medical Center here. And
17 this is why our culture is so important. Parking is
18 very difficult at our hospital, so we make the
19 surgeons park right here. Tony, this is for you.

20 So this is our story. In 1992, we had an
21 initiation of an IV insulin protocol throughout the
22 hospital due to several near misses with the use of

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1 SubQ insulin, mostly sliding scale insulin. Consider
2 that this was before any controversy of TGC in the
3 hospital. Consider that this was before the
4 introduction of insulin analogs. In fact, it was
5 before the introduction of Metformin. This in fact,
6 more than anything else, changed our culture of
7 insulin therapy in the hospital.

8 More history. In 2001 to 2002, we had over
9 six IV protocols and no SubQ protocol. So what we
10 decided to do was to standardize all of the insulin
11 orders. The Vandenberg SICU targets from 2001 seemed
12 too ambitious for us at the time, especially in the
13 non-ICU areas. So what we did was we targeted 180
14 milligrams per deciliter, with implementation of the
15 IV in the first part of the decade, and then in 2003
16 to 2004, we implemented a subcutaneous protocol. And
17 what we learned and what we did comparing the older
18 protocol on IV insulin to the newer one, was that our
19 newer IV protocol had to take into account the rate of
20 change of glucose similar to what the beta cell is
21 supposed to do when it works, as we felt this would
22 reduce the rate of hypoglycemia.

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1 So as an example, suppose a patient had a
2 glucose of 180 milligrams per deciliter, and one hour
3 after the glucose went down to 110. Well, this is a
4 big drop, and in our column method that we use at the
5 University of Washington, the recommendation would be
6 to go from four units an hour to 1.5 units per hour.
7 But since this was such a big drop, what we instead
8 put in the protocol for the nurses to do is to go down
9 to the less aggressive protocol, the more conservative
10 column. So we go from column 3 to column 2, and
11 instead of having 1.5 units per hour in this example,
12 the patient would receive 1.0 units per hour. Again,
13 this is all with bedside glucose monitoring on the
14 floor or in the ICU using our currently available
15 meters.

16 How did we do? Well, we went back and took
17 a look. We looked at 105 subjects, 8 percent of them
18 with Type 1 diabetes admitted to the hospital, mostly
19 all NPO, both medical and surgical. Fifty used our
20 new column protocol, 55 used our older protocol. The
21 populations otherwise were identical. And as you can
22 see, we had a dramatic reduction of hyperglycemia,

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1 both in the ICU -- that is critical care, or the non-
2 ICU side. And we also saw less hypoglycemia, down
3 under 5 percent, both with the ICU and the non-ICU
4 side.

5 What about subcutaneous insulin? Well, this
6 is a ? I think a much more difficult problem,
7 especially once one gets outside of the ICU setting.
8 Because there's little data in terms of efficacy,
9 safety, or outcome. Philosophies of insulin therapy
10 or disparate, even amongst those of us who are
11 considered experts. What allowed us to standardize
12 our approach in thinking, at least in my opinion more
13 than anything else, was the introduction of basal
14 insulin analogs, because it allowed us as clinicians
15 and eventually as patients, to think about different
16 components of insulin therapy with basal bolus
17 insulin, which really was not possible in the NPH
18 days, because there we were using the NPH insulin both
19 for basal and prandial needs.

20 So this is what we developed in 2004, where
21 you could see the resident could check off when the
22 glucose levels were monitored. And by the way, as an

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1 attending physician after 20 years, I have never
2 written an order at my own hospital because I'm not
3 allowed. That is a true statement. We have these
4 different goals, both in terms of pre-meal and in
5 terms of bedtime. Notice that the bedtime range is a
6 little higher. And notice we have breakfast, lunch
7 and dinner. We have nutritional orders, we have basal
8 orders, and the resident can just fill in the number
9 of units for basal for prandial insulin. But more
10 importantly than anything else, is it taught an entire
11 generation of young physicians how to think about
12 insulin. And never in my wildest dreams did I think
13 that something that we put as a tool to help patients
14 in the hospital for their diabetes would actually be
15 the most important tool to teach people how to think
16 about insulin, both on the inpatient side and on the
17 outpatient side.

18 We had correction dose insulin, both with
19 low algorithms based on their insulin dose, medium
20 algorithms, we had high algorithms, we could make
21 individual algorithms. I should point out very
22 quickly that I attend every July, and I'm here in the

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1 first or second week of July and I have a fourth year
2 medical student telling me that Mrs. Smith on the
3 fifth floor is on 20 units of basal insulin with
4 prandial insulin at 10, 10 and 12 on medium dose
5 correction. And I'm sitting there and I'm just
6 smiling, because she gets it. The medical student
7 gets it. And that's how I know we've done a good job.

8 Strengths and weaknesses of our protocol.
9 Well, we have a few strengths. We have found it to be
10 effective and safe. Standardized protocols ensure
11 best practices for all, and it teaches all involved in
12 patient care how to think about insulin therapy. But
13 we have many weaknesses. It's difficult to keep
14 ongoing teaching momentum about TGC once our diabetes
15 clinic moved offsite. Not particularly effective with
16 high-dose IV steroids. And we have three teaching
17 hospitals at the University of Washington; therefore,
18 we have three cultures. And therefore, the residents
19 and the students are getting three messages. Even the
20 fellows are getting three messages on what's the right
21 way to do this.

22 So are these protocols that I showed you as

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1 good as computerized algorithms? Well, there actually
2 is one study that looked at this. We were not part of
3 this study, unfortunately. This comes from
4 Glucommander, and this was published in abstract form,
5 comparing this computerized protocol to a column
6 protocol. Truth be known, it was the University of
7 Washington protocol. And the name of this
8 computerized algorithm is Glucommander. And what you
9 can see is that they did a little bit better with
10 Glucommander than our column protocol, and they also
11 did a little bit better with an average of 117 for the
12 column protocol versus 103 for the computerized
13 protocol. How clinically significant that is, I don't
14 know. But I think we did okay, at least in this
15 particular multi-centered trial, which as I
16 understand is still not published. Looking at
17 hypoglycemia, there was no difference, whether it's 60
18 or 40. The Glucommander did do better with
19 hyperglycemia above 200.

20 So my take is that we are unique. We had a
21 ten-year head start all because of several near-
22 misses. Our small successes need to be tempered by the

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1 realities of the need to educate a constant turnover
2 of physicians and nurses. What we do not necessarily
3 do well, high-dose steroids in patients eating on the
4 floor, transitioning off of IV insulin, and then a big
5 issue, discharging patients new to insulin into the
6 community.

7 Computerized algorithms should do better
8 than paper algorithms in most settings. The key is
9 the frequency of glucose testing and the knowledge of
10 the nurse operating the insulin drip. What we are
11 doing now is we have recently changed our IV protocol
12 so that all three of our teaching hospitals; that is,
13 the VA, Harbor View Medical Center and the University
14 of Washington Medical Center, we are all using the
15 same IV algorithms. It standardizes patient care, it
16 standardizes philosophy and culture of insulin use,
17 especially with the residents.

18 And this is really interesting. In talking
19 about what our target should be, the physician can
20 check, either 100 to 140 or 100 to 180. And I'm
21 sitting in this room last July arguing with surgeons,
22 especially neurosurgeons, that 110 should be the

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1 lowest on our target. And the surgeons are telling me
2 that I'm not being aggressive enough with the glucose.
3 I never thought I'd live to see the day. But that's
4 where we are. Our non-ICU targets are 100 to 180.
5 And we use separate protocols for inside of the
6 operating room and we need higher dose insulin,
7 especially for patients on steroids.

8 So in summary, our current practices of TGC
9 in the hospital is that despite the concerns about
10 hypoglycemia, the real problem in the United States in
11 the hospital remains untreated hyperglycemia, both in
12 the ICU and on the floors. Despite controversy about
13 actual targets, the real enemy is lack of attention to
14 glycemia in general and intimidation of insulin use
15 due to lack of training, and new concerns about
16 hypoglycemia. So thank you very much, and I'd be
17 happy to take any questions.

18 DR. MESOTTEN: Thank you for a nice
19 presentation. Dieter Mesotten from Leuven. I do have
20 a little bit of a problem. Tight glyceimic control,
21 you defined as somewhere between 100 and 180, which I
22 think is not really tight and you're reading an awful

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1 lot of hyperglycemia when you have these loose targets
2 from 100 to 180, or 100 to 140 in the ICU. Because
3 even we see in patients that have levels between let's
4 say 150 and 170, they've got a much higher risk of
5 dying compared to patients that have even moderate
6 blood glucose control.

7 DR. HIRSCH: Your point is well taken. What
8 we really have here is a problem with nomenclature.
9 Because if you go around the United States ? and maybe
10 it's different in the EU -- but when you look at the
11 data how things are, especially in the ICU, what you
12 see is that most people are above 180 and in fact most
13 people are above 200. And so if you go back and
14 become more academic and look at tight glycemc
15 control as 80 to 110, out in the real world when we're
16 seeing patients, at least in the United States, the
17 recommendations from ACE and the ADA that came out
18 last year where we say, the target should be less than
19 180, and we can go down to 110 -- I think for right
20 now with how we do in general looking at where our
21 baseline is, I actually think that's pretty
22 reasonable.

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1 I think if we really try to get, like you
2 said, to the tight glycemc control of 80 to 110,
3 whether it's in the ICU or on the floor where we
4 don't have the data, I just don't think that's
5 realistic with our current tools, and more
6 importantly, getting outside of the tools for a
7 moment, just with the current understanding of how to
8 do this and the understanding of insulin and the
9 issues with frequency of glucose monitoring. I just
10 think it's too difficult.

11 DR. MESOTTEN: That is my opinion. We first
12 have to improve our methodological techniques in order
13 to do proper trials, comparing it to media targets
14 versus the high and strict tight glycemc control. I
15 think we have to put more work on how we administer
16 insulin and how we measure the glucose levels, et
17 cetera, how we train our nurses the protocols, et
18 cetera.

19 DR. HIRSCH: I'm in total agreement.

20 DR. ANDERSON: Hi, Marcy Anderson from
21 Medical Automation Systems in Charlottesville,
22 Virginia. I just want to thank you and support

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1 everything you just talked about, because I'm in
2 charge of a product called the Roll's Report (ph). We
3 gather de-identified patient data from over 500
4 different hospitals in the United States, using a
5 particular blood glucose meter that's out there on the
6 market right now. And our data supports yours
7 absolutely. We just saw that in those hospitals with
8 less than 40 milligrams per deciliter, we saw 4.8
9 percent. In the ICUs that had less than 40.12 percent
10 and the non-ICUs, .36 percent.

11 DR. HIRSCH: Can I ask your N, your
12 denominator for that?

13 DR. ANDERSON: 50 million.

14 DR. HIRSCH: 50, 5-0?

15 DR. ANDERSON: Yes.

16 DR. HIRSCH: 50 million.

17 DR. ANDERSON: Yes.

18 DR. HIRSCH: Okay.

19 DR. ANDERSON: That's for 2009. This was
20 actually 2008 data, so for all tests we had 29 million
21 ICU tests, 7.6 million and non-ICU, 22.08 million. We
22 aca5tulaly did a poster on this for Dr. Klonoff's

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1 diabetes technology meeting back in November. We're
2 in the process of doing a paper for the 2009 results.
3 And yes, we're seeing a high percentage over that 180,
4 over that 200 milligrams per deciliter. We're still
5 seeing 25 percent of those patients are in that hyper
6 range.

7 DR. HIRSCH: Correct.

8 DR. ANDERSON: So again, we're seeing hyper
9 is still a major problem. The hypo isn't nearly as
10 much of a problem as we anticipated. And for
11 averages, we're seeing in the 160s range for ICUs down
12 into the low 150s. That's a median for all of these
13 different hospitals. And again, they're different
14 sizes, different shapes and focus across the U.S. But
15 just want --

16 DR. HIRSCH: I appreciate your comments.
17 Thank you very much. Last question before lunch.

18 DR. KLONOFF: Irl, David Klonoff, Mills-
19 Peninsula Health Services. What type of blood glucose
20 monitoring systems are you using? Do you think that
21 current blood glucose monitors with the accuracy that
22 they have are sufficient for the type of results

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1 you're getting, or if not, how much better do you
2 think they need to get?

3 DR. HIRSCH: Well, thank you for your
4 question. The answer is, what our hospital is using
5 right now is we are using the Roche AccuChek system.
6 Do I think they're accurate enough? I'd like to see
7 it more accurate. Tony's point I think is very good,
8 looking what he's done down the highway from us in
9 Portland. My issue is, I'm always putting up the
10 flags, getting back to something that was discussed
11 yesterday and I was not here yesterday? the issue of
12 the GDH/PQQ. Because there are little pockets in the
13 hospital, that as much as I try to make sure that
14 there are no problems, sometimes problems can exist.
15 I intercepted one a few weeks ago, for example, in the
16 cath lab, where I had a peritoneal dialysis patient
17 going in there and it was not on their radar.

18 So it's continued education about that
19 particular issue with interferences. We are probably
20 always going to have to do education. But to your
21 specific point about accuracy -- independent of the
22 interferences, I would definitely like to see better

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1 accuracy. This 20 percent issue, especially for the
2 number of insulin-sensitive Type 1 patients who come
3 in, where they are sensitive to one and two units of
4 insulin, making potentially huge differences in their
5 glucose, much more of a concern for me in a hospital
6 that we see more Type 1 patients than any hospital in
7 the State of Washington than in the more resistant
8 Type 2 patients where relatively small differences in
9 insulin are not going to have a big impact on outcome.

10 DR. KLONOFF: Have you seen any data that
11 would let you select a target that you'd like to see
12 for accuracy, like 15 percent, 10 percent, any number?

13 DR. HIRSCH: I mean, the lower the better.
14 Where the issue comes in, quite frankly as I
15 understand it, has to do with how long does the test
16 take and how costly are the strips going to be. To
17 answer one of the initial questions that I raised at
18 the beginning, is cost right now an issue in the
19 hospital in particular when we do strips? To my
20 knowledge, it's not an issue at all, but what is an
21 issue is the time it takes to do the test, because the
22 time of the nurse now becomes a real issue. Because

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1 that's much more costly than the strip itself, and
2 nobody thinks about the time it takes the nurse to do
3 the finger stick glucose. And so if we get an
4 accuracy down, let's say 5 percent but it takes 5
5 minutes to do it, I'm not sure it's worth. So there's
6 all these things that have to be retaken into
7 consideration.

8 DR. KLONOFF: That's really difficult,
9 because one of the trade-offs that the glucose
10 monitoring companies might have to use is a longer
11 time for the measurement to get more accurate.

12 DR. HIRSCH: And that's going to be the
13 problem. That's where the rubber's going to really
14 hit the road.

15 DR. KLONOFF: That was a great presentation,
16 as always. Thanks, Irl.

17 DR. HIRSCH: Thank you. Okay. That ends
18 our morning Session 3. I thank you very much. It is
19 now lunchtime. We will meet back here for the Panel
20 discussion at 1:30. Enjoy your lunch.

21 (Recess for lunch)

22 DR. HIRSCH: So we're still waiting for a

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1 few of the panel members. Is Dr. Rollins still here
2 or did he leave? Dr. Rollins left. Oh so -- okay,
3 okay. So it's -- it's a smaller panel, and we are in
4 stereo. Before we start, I want to introduce Dr.
5 Patricia Beaston who is joining our panel. She's a
6 medical officer at the FDA and a graduate of the
7 Medical College of Pennsylvania, and welcome to the
8 panel. And I think what I'd like to do -- I think
9 we've all had some very stimulating conversation at
10 lunch about what we heard this morning and before
11 opening this up for full discussion, I'm going to put
12 somebody on the spot here. And in particular, I'm
13 going to ask Dr. Beaston who heard everything this
14 morning and I know I heard at lunch with my own ears
15 you had some interesting comments about what was said
16 this morning. I'm curious -- what are your sort of
17 top level thoughts and specific concerns you may have
18 had about what you heard this morning?

19 DR. BEASTON: Well I guess, one of the main
20 concerns is there doesn't seem to be a consistent
21 agreement on what is tight glycemic control. I mean,
22 is it normal glycemia? Is it better than what we've

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1 been doing? You know, what -- what are the goals?
2 And that will help inform the needs for performance of
3 whatever we use for glucose monitoring based on what
4 the levels of glycemic control are. The other is that
5 there doesn't seem to be a consistent use of the
6 definition of hypoglycemia whenever trials are done.
7 Some use 70, some use 60, some use 50. So I think
8 it's important if people want to be able to compare
9 trial to trial and end points that there's some
10 consistency. Certainly they can use other targets, but
11 there should be some approach that makes it easier for
12 people to compare outcomes. And the -- another is the
13 concept of time to get a reasonable result. So I
14 understand that nurses are really busy. I understand
15 that you don't want to have to wait five or ten
16 minutes to get a great result. But if you're trading
17 five or ten seconds for a minute but you're going from
18 a 20 percent error to a five percent error, is that
19 not a reasonable exchange? One of my favorite things
20 that I was always reminded of is, if you don't have
21 time to do it right the first time, how do you have
22 time to do it over? So if you're not reasonably

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1 assured that the glucose level that you're making your
2 management decisions on is any good and you're
3 spending time repeating it or you got it wrong and now
4 you have to go find the D50, or you have to treat the
5 patient otherwise for the severe hypoglycemia, what's
6 the trade off for that time? So there's a bunch of
7 clinical issues that sort of go into how you're going
8 to figure this all out that people really haven't
9 discussed too much that I'd like to hear about.

10 DR. HIRSCH: Okay. So there were -- there
11 were three topics and I think two of them -- the first
12 two, we can separate from the last one in that part of
13 what we are talking about is nomenclature when we talk
14 about tight glucose control in the hospital. We are
15 talking about definitions and what we -- what I showed
16 you, what we do at our hospital -- we don't call it
17 tight glucose control or tight glyceemic control.
18 That's just sort of what the literature calls it, and
19 it's almost taken on a life of its own with all of the
20 inpatient studies. But I actually think your point is
21 very well taken. We don't have a good definition of
22 it. And it's sort of like anything. When we talk

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1 about a topic, we need to make sure we are all talking
2 about the same thing. And this is probably -- and
3 again, I agree with your comment -- no more as
4 important if mostly important for the topic of
5 hypoglycemia. A few years ago the American Diabetes
6 Association came up with a biochemical definition of
7 hypoglycemia which is less than 70 milligrams per
8 deciliter, which is different than the accepted
9 definition of severe hypoglycemia on the outpatient
10 side which is requiring the assistance of another
11 person which is very different than something that on
12 our AACE-ADA committee we could not find where the
13 definition of severe hypoglycemia in the ICU being
14 less than 40. We could not find where that actually
15 originated from. And -- and it almost seems to me,
16 and I'd be curious what other people think, that the
17 first thing that we need to do as a group is come up
18 with a set of agreed upon definitions. Because right
19 now, our definitions for these topics are just not
20 consistent. Not only between societies and between
21 disciplines, but maybe more importantly between
22 hospitals at the patient level. I'm curious if anybody

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1 has any other comments on that point. Either in the
2 audience or -- yeah, go ahead.

3 DR. MESOTTEN: I do have some comments. I
4 mean when we talk about tight glycemic control, we
5 have to back to all the clinical trials that have been
6 done. So three in Leuven, the NICE-SUGAR trial, VICEP,
7 GLUCONTROL. I mean they all had an intervention group
8 80 to 110. So I think when we're talking about tight
9 glycemic control -- tight -- I'm not a native English
10 speaker but tight means "very narrow." I mean that's
11 80 to 110. I mean other types are intermediate or no
12 glucose control. But when we're talking about tight -
13 - whether it's good or bad, I mean that's a different
14 issue. But that's very narrow, 80 to 110, looking at
15 the lowest risk association in a J-shape curve.

16 DR. HIRSCH: So, so, you would agree though
17 that no matter what we decide we all need to be in
18 agreement, whatever it is. Okay. So then my next
19 question coming back from this morning -- I mean we
20 looked at some of the U.S. data in terms of how we do
21 with control, and the answer is not very well. What
22 is your impression in terms of tight glycemic control

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1 in the EU or even in your country? Do you guys do
2 better than we do?

3 DR. MESOTTEN: I don't want to go into a
4 comparison versus USA because it always -- politically
5 incorrect to do.

6 DR. HIRSCH: Smart man.

7 DR. MESOTTEN: I mean we definitely in
8 favor of tight glycemic control and we still do it in
9 all our patients. I mean, I often go around the
10 country and see many, many colleagues in Belgium and
11 Netherlands, and namely also Germany. Most of them,
12 they use a modified version of tight glycemic control
13 and what they do -- they bring the upper limit of the
14 tight glycemic control range to about 140, 150. But
15 they leave the lower limit to about 80. So they would
16 never, ever tolerate 180 because that's the level we
17 will tolerate for general hospitalized patients, where
18 you only measure like twice a day maybe. But in the
19 ICU I think we should be able to do better. If you
20 look at the J-Shape curve. If you tolerate levels up
21 to 150-160, you significantly impair patient survival.

22 DR. HIRSCH: So I want to make sure that I

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1 understand that correctly. You will measure it twice
2 a day even for somebody receiving four shots a day in
3 the hospital -- not in the ICU, but in the hospital?

4 DR. MESOTTEN: Clinical practice learns
5 that that's the case, yes. And I agree that that's
6 not appropriate to do. But, I mean, if you're on a
7 surgical ward, surgeons -- they are not really
8 interested in glycemic control, and they don't take
9 the proper measures to do control.

10 DR. HIRSCH: Hear that Dr. Furnary?

11 DR. FURNARY: I was waiting for an opening.

12 DR. HIRSCH: Okay.

13 DR. FURNARY: So -- and I moved closer so
14 that I -- because I don't have a microphone, but -- I
15 think, first of all, surgeons in this country -- this
16 country is different than Europe. Actually Europe, I
17 think the data show, have tighter glycemic control
18 than we do. The mass data shows that our average tight
19 glycemic control in this United States has an average
20 of about 161 the last I looked at it, and in Europe
21 it's definitely lower than that. I think it's in the
22 140s or 130s. The important part about tight glycemic

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1 control to define what Arleen was -- or what -- I'm
2 sorry, Patricia, was asking about was that one has to
3 look at what outcome measure you want to improve. If
4 you just want to eliminate infection, all the data
5 shows -- there is no data that does not show -- that
6 150 is better than 180. You just have to be below 180
7 because all the biochemical and physiologic things
8 that affect the immune system kick in at 10 millimolar
9 or 180. If you want to affect mortality, you need to
10 at least be below 150 and according to the J-shaped
11 curves you need to be between 80 and 120. If you want
12 to affect transfusion, our data shows -- and I think
13 Reeds (ph) also shows you need to be less than 140 if
14 you want to reduce transfusion. Our data shows that
15 if you want to reduce arrhythmia, we haven't found a
16 low end to that and that's why we're at 70 to 110
17 because arrhythmia is almost non-existent in our
18 population now and the deaths that we prevent, half
19 are prevented from the elimination of arrhythmias and
20 half are prevented from the elimination from heart
21 failure. So how tight is tight? I think the -- it
22 depends on the patient population and the outcome

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1 you're asking about. So -- and that answer is
2 scientifically out there in the literature.

3 DR. HIRSCH: Tony, I think to your point,
4 Mercedes Falciglia from the University of Cincinnati
5 actually looked at a very large population of vets
6 showing that the glucose control -- whatever you
7 consider tight -- is dependent on their primary
8 diagnosis.

9 DR. FURNARY: So --

10 DR. HIRSCH: And there are some diagnoses
11 that it didn't make a difference and that's -- that's
12 important too.

13 DR. FURNARY: Yeah, it's a really
14 interesting piece. And, you know, I didn't get into
15 it earlier today but in my mind there are actually --
16 it's why I -- there are actually six different things
17 that affect glycemic control. And only one of them is
18 the meter. It's the meter, the pump, the thing that
19 delivers the insulin, the person -- the protocol, the
20 person that interacts with the protocol, and the
21 patient. Every single one of them affects how well we
22 do glycemic control, the rate of hypoglycemia, the

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1 outcome. It's one of the reasons that -- I mean,
2 there are some isolated heart surgery populations that
3 we've shown no improvement in mortality but a huge
4 improvement in infection. So each patient population
5 is different in terms of tight glycemic control. But
6 not as it pertains to this meeting. Not different in
7 terms of how we measure glucose.

8 DR. HIRSCH: So, hold that thought because
9 getting back to how we started this conversation and
10 the definition of tight glycemic control -- and it is
11 relevant as far as meter accuracy is concerned. From
12 what I'm hearing from all of our discussion, is it
13 possible that tight glycemic control is dependent on
14 the population being discussed and so there for those
15 numbers also potentially could vary based on the
16 diagnosis of that patient?

17 DR. FURNARY: Yeah, that's made exceedingly
18 evident in the VICEP trial. Septic patients have a
19 very high susceptibility -- and Dieter can comment on
20 it, so can Richard -- very high susceptibility to
21 hypoglycemia. Cardiac surgery patients not so much.
22 And so I think the patient population really matters.

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1 And so we now have one -- you know, the Portland
2 Protocol has six different target levels because we
3 don't believe everybody should be at the same target
4 level which is a whole different discussion, but one
5 of our target levels is for sepsis. And our sepsis
6 target level is 130 to 165 because septic patients are
7 more susceptible to hypoglycemia. So the answer to
8 your question is yes.

9 DR. HIRSCH: So -- and this gets back to
10 what Rich is doing with the ADA and the Professional
11 Practice Committee on the outpatient side with ACCORD
12 (ph), with what we're learning with long-standing Type
13 I Diabetes -- is it -- are we sophisticated enough as
14 a medical community to have different targets?
15 Whether it's A1C on the outpatient side or glucose on
16 the inpatient side to have different targets for
17 different populations? Because I haven't seen that
18 we've been able to do that very well on the outpatient
19 side.

20 DR. FURNARY: Well, we have it in our
21 hospital.

22 DR. HIRSCH: You do?

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1 DR. FURNARY: Our cardiac unit is the only
2 unit that's 70 to 110. Our ICU is 80 to 120 and our
3 floor is 100 to 150. And we do it on the floor which
4 is a huge -- we can get into that. We, like you, have
5 done it on the floor since 1995. Insulin drips -- on
6 the floor -- point of care meters. Hypoglycemia less
7 than -- in the floor 100 to 150 -- less than two
8 percent. So yes, you can have different target ranges,
9 but you have to have the same protocol. I think when
10 there's six different protocols and they're all
11 written differently and people aren't familiar with
12 them, that's a problem.

13 DR. HIRSCH: I want to ask other people on
14 the panel -- do you think we can have -- in any given
15 hospital; can we define tight glyceemic control
16 differently? Not so much based on the ward, but based
17 on the -- or where they are in the hospital -- but
18 based on the diagnosis. I mean is that something that
19 you think we can do? Trish -- Rich.

20 DR. BERGENSTAL: Well, I mean I think this
21 is the perfect discussion. This is what we need and I
22 don't know if we'll solve it today, but this will be

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1 the going home work, I think, for panels of people to
2 do. Because I was initially thinking, "Well, can we
3 just say ICU versus floor? Can we say -- optimal is
4 80 to 110 and current target 110 to 140 and acceptable
5 under 180, but then it's different from the -- now I'm
6 hearing it's not just the unit and the floor, but it's
7 the patient type on each of those. So, I hope we
8 could sort that out. I mean, as you say, we're
9 struggling with that on the outpatient side. We get
10 criticized to say, "Oh, you say less than seven for
11 everybody. That's not safe." Well, let us tell you
12 who the people that it's not safe for and make an
13 exception, but don't treat everybody to less than
14 eight just because there's ten percent who shouldn't
15 be less than seven. So I like this discussion. I
16 don't have the answer today.

17 DR. HIRSCH: Go ahead, Patricia.

18 DR. BEASTON: Well, during my fellowship I
19 took care of a lot of transplant patients. I took
20 care of liver transplant patients, and cardiac
21 transplant patients, and renal transplant patients.
22 They were all different patients. And you had to not

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1 only figure out what kind of transplant they had,
2 where were they on their immuno-suppressant regimen,
3 were they getting fed, were they not getting fed. I
4 mean, it gets to be very complicated. So, for people
5 who do this all the time, you really can get into tune
6 with what individual patients need. And I think it's
7 reasonable to have flexible algorithm that goes
8 through a certain process, but that the physician who
9 is in charge of that patient can say, "For this
10 patient, given his or her history and these
11 medications, this is what I think is appropriate for
12 them at this time." With the understanding that if
13 something changes you need to be made aware because
14 that algorithm can be drastically changed. I can't
15 tell you how many times they changed the immuno-
16 suppressant drug and then didn't notify the endocrine
17 service and then the patient got into trouble. So,
18 you -- it's not a one-size fits all, but I think that
19 there's a process by which you can take everybody
20 through that they'll be comfortable with the process
21 and have enough flexibility that they can follow what
22 those instructions should be for that patient.

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1 DR. HIRSCH: Go ahead, Dieter.

2 DR. MESOTTEN: I would strongly
3 disagree with certain opinions. I mean first of all,
4 I think we should think scientifically first. There's
5 a difference between randomized clinical trials and
6 implementation studies. And I think from
7 implementation studies, we cannot delineate different
8 operations that would -- may require different target
9 ranges. When we're talking about, for example, the
10 VICEP trial, overall the study was under power to
11 detect a difference at all. So you cannot draw any
12 conclusions out of it then say like, "Okay, in septic
13 patients, we'll have to use different target." I mean
14 these are non-evidence based statements that you have
15 to use something intermediate. For example, if you
16 take the NICE-SUGAR trial and you say, "Okay, I
17 believe the other." Then you should stick to 144 to
18 180 mg/dl. There's no evidence to go for somewhere in
19 between 120 to 140. And from a general point of view,
20 I think it's very dangerous to go back to the years
21 but every physician will decide, For this patient, I
22 think this one is the best. I mean we have to take

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1 into account evidence-based medicine and it's
2 different trials. And nothing that you can decide for
3 your patients is the best it's going to be. I mean,
4 for example, if you compare it to the airline industry
5 -- I mean you've got different airplanes at different
6 airports, etc. They've got very much standard
7 operating procedures and it works really well.
8 There's definitely a need for standardization and not
9 go back to different targets, different techniques,
10 different protocols. It really confuses people. And
11 that's the difference between the
12 Leuven studies where everything was
13 basically standardized, and all the confirmation
14 multi-center trials where everyone was let free and
15 there was no standardization at all. I think that we
16 should stick to one target, get our nurses used to it,
17 work with one protocol, one type of infusion, one type
18 to measure blood glucose levels, to improve outcome.
19 And that's the way to go. And I think there's an
20 awful lot of work to be done on the methodological
21 side -- point of view: measurement, protocols, etc.
22 But we should really think scientifically, and a

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1 randomized trial is much stronger than implementation
2 studies.

3 DR. HIRSCH: Okay, go ahead Courtney.
4 You're itching here.

5 DR. HARPER: Well, I just want to actually
6 thank everyone for this particular discussion -- both
7 this morning in the presentations and now. Because it
8 highlights the importance of, I think, delineating
9 what is needed in this area and evidence that base
10 medicine is obviously the highest bar. But it also
11 highlights some of the maybe non-consensus in the area
12 about what to do, which -- you know, so this
13 discussion is good and hopefully maybe one outcome of
14 this meeting is that there will be some efforts to
15 move forward and maybe to find some of these terms
16 could help first, and then some of these things. The
17 reality for us, though, is that we're being faced
18 right now with situations where we're being asked what
19 studies are necessary to show that my device can be
20 useful for this. And whether they be a blood glucose
21 meter or some other type of technology, you know, we
22 would like any input that we could get as to how we

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1 can actually try and demonstrate the performance at a
2 level that's necessary for this patient population and
3 this use. So -- so I also encourage you all to think
4 about that and if you have some input today we'd love
5 to hear it, and if you want to talk with us further,
6 we'd love to actually hear from people and their
7 opinions on what types of studies are really needed
8 here.

9 DR. HIRSCH: Ms. Mann, you've been very
10 patient.

11 DR. BEASTON: I'm sorry -- I just wanted to
12 respond to Dieter one second. I mean, airports do
13 have protocols. But I can assure you that you cannot
14 land a 747 on the same runway that you can land a
15 commuter plane. I mean, so there is flexibility
16 within what the needs are for any situation. And to
17 say that everybody is going to fit in a box, I think
18 is also a mistake because patients can come to harm
19 when you make assumptions that any patient is
20 represented by whatever clinical trial that you did.

21 DR. HIRSCH: Thank -- thank you. Go ahead.

22 MS. MANN: Elizabeth Mann from the Army Burn

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1 Center again. I've been building up, so give me a
2 minute because there's a couple points that are really
3 important here. I think the issue about individual
4 patient targets is exactly right. I think different
5 patient populations definitely need different targets,
6 and I believe that some of the work done on diabetics
7 - - acute and chronic diabetics or in the acute
8 setting - - they probably need a little bit higher
9 target because physiologically they're used to living
10 at a higher target. How do you do that? Well, we
11 have just been working with a computer decision
12 support system. And I also believe that it's
13 certainly within the realm of possibility today to
14 program those for a diabetic patient, for a burns
15 patient, for a TBI patient, for different populations
16 that the provider can select. The computer does all
17 the work. The nurse isn't bogged down with, you know,
18 multiple -- several column protocols that they have to
19 weed through. And those do get very complicated. The
20 more complicated the protocol, the better it works,
21 the harder it is for nursing. And I'm a nurse so,
22 that's one of the things we do. So that being said,

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1 what is the best target -- is 80 to 110 really
2 realistic? What we discovered in our work and
3 discovering the glucometer error, is that when you
4 have an anemic patient and they're at 80 to 110 but
5 their hematocrit is 20, which is the ABEAR (ph) target
6 -- 21 percent, which is half of normal, they're really
7 sitting at a glucose of 60/65 to 90/95. We're forcing
8 them into that with this tight glucose control. So
9 what are the counter-regulatory mechanisms that get
10 activated when you force a patient using I.V. insulin
11 into that range? It causes more variability, they
12 start spiking, you give them more insulin, they start
13 dropping and you create a vicious cycle. And what
14 we've observed and published is that when we did the
15 mathematical correction for hematocrit, we stopped
16 having the occult hypoglycemia, we stopped having that
17 variability and it was a lot easier to control the
18 patients. So that's one, I think, very valid point
19 that the accuracy of the glucometer is absolutely
20 essential to safe, tight control -- whatever you
21 prescribe.

22 DR. HIRSCH: So let me ask you a question.

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1 And this is critical. Going back to point number
2 three from Patricia earlier. Would you be willing for
3 one set of patients where you are trying for normal or
4 near normal glycemia -- would you be willing to use a
5 more expensive strip that took up to three, maybe five
6 minutes, for that population, but for another
7 population where you are not trying for that tight of
8 control, using a different meter with different
9 accuracy, maybe closer to what we are using today?
10 Would you be willing to do that?

11 MS. MANN: With all due respect, I've
12 tested all five glucometers available, personally.
13 The new four channel glucometer is almost identical to
14 the reliability in the lab and that one takes, I
15 think, seven seconds. Ten seconds? Six seconds.
16 Okay, there's no extra time. There's no need to
17 develop a better mousetrap because it already does
18 exist. Our hospital has made the executive decision
19 to change to that technology, but in the mean time we
20 -- in the Burn Center, continue to use the
21 mathematical correction. I re-looked at my data from
22 our published paper. When you use any of the big four

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1 glucometers that are available, you can correct them
2 at the point of care and get within less than ten
3 percent error at every hematocrit level, and in fact
4 at the very low hematocrit levels, the accuracy is
5 less than eight percent. So, we can do it now and
6 there's no extra cost, there's no extra time, there's
7 no extra investment. And that's the bandstand that I
8 keep -- or soapbox I'm jumping up and down on today is
9 that the technology is there. Whether this one
10 company can produce enough glucometers for the entire
11 United States -- now I don't think so. So, there
12 needs to be some intermediate thing.

13 DR. HIRSCH: Okay.

14 MS. MANN: And then -- oh -- should I say
15 it out loud? It's the Novasure Stat Strip, which is
16 the four-channel glucometer. And those data we just
17 published in critical care medicine in February that
18 we did in the Burn Center. But I'd also like to say
19 that as far as protocol. It is -- it is -- the
20 glucometer -- and it's been said over and over again -
21 - is the tiny part of tight glycemic control and it
22 depends on the nurse and on the protocol that you're

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1 using. We just did a study that's going to be
2 published on the computer decision support, and in a
3 burn patient who's hypermetabolic, has no liver, no
4 muscle stores, poor glycemic control -- this is a very
5 safe method. And our rate of hypoglycemia, using our
6 regular point of care glucometer that we do correct
7 with hematocrit -- our rate of less than 40 is .1
8 percent. So it can certainly be done, but I still
9 think that computers are the way to go. You can't
10 standardize among providers and among centers,
11 especially to do a big study that we need, without
12 this type of control. And let the computer -- I mean
13 a computer can land a jet plane -- I think it can help
14 us to guide some therapy based on the patient's
15 response, and tailor it to that individual patient.

16 DR. BEASTON: I have a question. Are you
17 doing capillary glucoses or are you using the meter
18 and then using venous blood or arterial blood on it?

19 MS. MANN: We only use arterial and venous
20 blood in the Burn Center. And in the studies that I
21 published, it was always arterial or central blood --
22 no capillary blood. Anyway, thank you very much -- I

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1 feel strongly about it.

2 DR. HIRSCH: Okay. Thank you for your
3 comments. So -- so, the question that I have for the
4 whole group is, you're hearing a few opinions. We're
5 curious -- what do we need to have developed that we
6 don't have now? I mean -- or do we have what we need
7 to have developed and we didn't even need to have this
8 meeting developed? Because I don't believe that. But
9 I'm curious, for where we are right now in terms of
10 where we are with our strips and the precision and the
11 accuracy, I'm curious if we can have some discussion
12 on where we need to go with this technology. Please
13 introduce yourself, sir.

14 MR. SOUTHERLAND: Hey. Phil Southerland.
15 Team Type I, Atlanta, Georgia. So, I agree. Science
16 tells all and a large randomized trial could do a lot
17 for us. It's just what is large randomized trial? So
18 in a "N equals 2" study, I put a continuous glucose
19 monitor on my best friend who does not have diabetes,
20 and then over a five day stretch, I try to mimic my
21 blood sugar to his. So, the question being, could we
22 put a large- scale randomized continuous glucose

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1 monitor study on non-diabetic patients -- people --
2 and find out what is the norm? What is the goal?
3 Where should we be striving for? And then use this
4 technology, the CGM which I use and have used for the
5 past two and a half years straight, to try and mimic
6 people without diabetes, thus preventing complications
7 that often stem from this disease. Has that been
8 done, and if not, is it something that could be looked
9 into?

10 DR. HIRSCH: So if we were going to do a
11 CGM study in a hospital, specifically an ICU, what
12 would the -- would the end point always have to be
13 mortality? Could we use other end points?

14 MR. SOUTHERLAND: I prefer to stay alive,
15 so. . .

16 DR. HIRSCH: I mean it's important because
17 what we heard today, to do a study powered to show
18 mortality with the sort of blood sugars we're talking
19 about like we're seeing in NICE-SUGAR; if I remember
20 the number it was 70,000 people. So I think one
21 question -- and don't get me wrong, there's probably
22 no bigger CGM proponent in the audience than me right

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1 now, but I'm very concerned that once we start doing
2 CGM studies, prospective, randomized, multi-center
3 studies, we have to be very careful where we set the
4 bars. Because the power to see the mother of all end
5 points -- mortality -- is so high. We would need so
6 many people.

7 MR. SOUTHERLAND: Well, I mean, could we
8 look to the average among 2,000 people without
9 diabetes say --

10 DR. HIRSCH: I mean there are other end
11 points than mortality, and specifically I think the
12 big one here we're talking about is hypoglycemia. Why
13 don't we -- why don't --

14 MR. SOUTHERLAND: Well hypoglycemia, but
15 also to your point and what you say in many of your
16 talks is the standard deviation -- the variability,
17 and find out what does a person without diabetes do,
18 and then can we try to aim for that as a goal.

19 DR. HIRSCH: Right, but we need to have
20 hard end- points. And looking at statistics and math
21 isn't going to cut it for what we're talking about
22 here.

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1 MR. SOUTHERLAND: Fair enough.

2 DR. HIRSCH: Why don't we move on?

3 Anybody? Anybody else up here? If not, the surgeon
4 from Portland.

5 DR. FURNARY: Yeah, I want to address your
6 question. I'm a surgeon from Portland. The question
7 is where do we need to go? What tools do we need?
8 And I'm going to restate, Irl, that I don't think that
9 the focus of this -- these two days, is proof of
10 concept, or disproof, or trying to figure out what
11 target level TGC should be at. And I think linking
12 clinical outcomes to an approval of a CGM or a point
13 of care device is not what the FDA is all about. Now
14 -- Patricia and Courtney --

15 DR. HARPER: That depends on what somebody
16 claims. So if somebody comes in with a device that
17 says this device is to achieve tight glycemic control
18 in the ICU, then that is what we actually need to
19 show. So. . .

20 DR. FURNARY: I think that once we get to
21 the closed-loop pancreas -- the artificial external
22 pancreas -- that's the goal, but I don't think that's

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1 a current goal.

2 DR. HARPER: I'll be -- I'll be -- you know,
3 the artificial pancreas is definitely a great effort,
4 and we're working on that. It's definitely a couple
5 of years away until we get something that is as
6 advanced as that. But there are stages in between
7 that that may come more quickly. And there's also
8 similar products under development that are not
9 necessarily what you would think of as the artificial
10 pancreas, closed-loop, that may come in advance of
11 that. So, you know, this stage-wise approach to get
12 to the point of having these technologies, you know,
13 we may see that sooner. And so we need to figure out,
14 you know, how to do these studies, and what types of
15 end points, and how good does the performance need to
16 be. So, it may be that we don't know that, but it may
17 be that we do. So one question I would have for you
18 is that I've heard a couple of conflicting statements
19 here. So on the one case, I've heard people say, "You
20 know what? We don't need that many measurements. You
21 know, if we have too much data, it doesn't help our
22 algorithms," and things like that. And on the other

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1 hand I've also heard things to say, "If we know the
2 direction of change, and the rate of change, and if we
3 have more measurements, maybe we can be better." So
4 which is it?

5 DR. FURNARY: It's a -- that's a perfect
6 segue to what I got up to say. And, what I got up to
7 say was I'm going to readdress Dieter -- Dieter's
8 question about whether this can be done with current
9 technology, and what's different about why can Greta
10 do it in Leuven, and why can I do it in Portland, and
11 why can no one else do it? Someone asked that
12 question. And the reason is the frequency of
13 measurement. In Leuven it can't be done with point of
14 care devices because the most frequent that they
15 measure the glucose is every hour when it gets low.
16 And so that -- but in Portland, the protocol says that
17 when you get low you measure every 30 minutes. And
18 what happens is the more frequent you take
19 measurements, it starts to get rid of some of that
20 variability. And so if you have a measurement that's
21 every 15 minutes apart, and it has a 15 percent
22 deviation, that's probably as good as a measurement

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1 that's every minute that has a 20 percent deviation
2 because you're going to start narrowing down. The
3 cluster analysis of what goes on gets you a better
4 reading. The different is -- and the reason
5 hypoglycemia doesn't matter in Portland is because any
6 time we get down there, we're measuring it every 30
7 minutes and they don't -- the average time in
8 hypoglycemic range is 33 minutes. In Leuven, it can't
9 be less than an hour.

10 DR. HARPER: Can I get you to clarify one
11 thing?

12 DR. FURNARY: [Affirmative.]

13 DR. HARPER: So are you talking solely about
14 an imprecision? So obviously if you measured more
15 frequently, you're going to reduce the impact of
16 imprecision a little bit.

17 DR. FURNARY: Yes.

18 DR. HARPER: But are you also talking about
19 a bias, or --

20 DR. FURNARY: No, I'm talking about
21 imprecision. And so, what I'm saying is, yes, to
22 answer Dieter's question earlier this morning -- and I

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1 left you with this -- is that yes, tight glycemc
2 control can be done with current devices if used
3 frequently enough. Now, do we need -- so what is that
4 -- what about everyone else? Not everybody's going to
5 measure every 30 minutes, or every 15 minutes because
6 it takes a lot of time. This is why we need -- and
7 this is the answer to Irl's question -- where do we
8 need to go? We need to go to continuous glucose
9 monitoring devices. Because continuous information
10 gives us much more information to prevent hypoglycemia
11 and I would rather have a measurement every minute
12 that has a 10 or 12 percent deviation than a
13 measurement every hour that has a five percent
14 deviation -- a five percent MARD. Because I can steer
15 the patient -- we can steer the patient where we want
16 them to go. That's the difference. And so, that
17 really brings us full-circle to where I think the FDA
18 needs to be focusing on, and this is probably the
19 tough question is -- how do you approve a CGM device?
20 My point -- earlier point is, coming back around full-
21 circle, is you don't approve a CGM device based on the
22 outcomes; you approve it based on how good it is at

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1 telling you actually what the blood glucose level is.

2 DR. HARPER: Right. And so, you know, the
3 types of patients that we need to look at, the values
4 of blood glucose that are most important. I mean I
5 think that we did get some of that information today.
6 But one thing -- you know, some of the things you say
7 make me wonder -- is it -- it still probab -- they
8 need to be equally accurate --

9 DR. FURNARY: Yes.

10 DR. HARPER: But it can tolerate more
11 imprecision perhaps -- is that what you're saying?

12 DR. FURNARY: Probably -- I don't even
13 think you need to tolerate more -- I think they're
14 going to be equally or more accurate. But what I'm
15 saying -- what I'm saying to Dieter to answer the
16 question earlier is, you can use current devices if
17 you use them frequently enough. You get rid of that
18 and make it available to the common man by making it
19 continuous. And it's going to still improve. And
20 most of the continuous devices that I've seen are at
21 least as good as, if not better than, the current POCT
22 devices in terms of MARD.

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1 DR. HIRSCH: Now the one thing, just to be
2 clear, Tony, with the CGM devices -- and I can't speak
3 for the ones in the future, but at least the ones now
4 -- they are dependent on the accuracy of the point of
5 care capillary glucose level. And if that is off by
6 19 percent, you potentially have a real problem if the
7 MARD is 15 percent on the CGM device.

8 DR. FURNARY: I think -- and I'm familiar
9 with one, two, three, four, five, six of them. I'm
10 familiar with six of them. And that's a correct
11 statement, but it's only correct if you use a point of
12 care device to get your baseline to basically
13 calibrate the device.

14 DR. HARPER: All CGMs are currently
15 calibrated with the blood glucose meters.

16 DR. FURNARY: No. They can be calibrated
17 by a lab measurement. They could be -- you can
18 calibrate them by anything you want to calibrate them
19 by. You can calibrate them by mass spec if you
20 wanted. You can calibrate by anything you want to
21 calibrate with.

22 DR. HARPER: I was talking about the labeled

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1 performance.

2 DR. FURNARY: Oh, okay. I don't know the
3 labels

4 --

5 DR. HIRSCH: We're all into labels here,
6 Tony.

7 DR. FURNARY: I do agree with you that
8 whatever you calibrate it with, you're going to be
9 limited to that amount of deviation.

10 DR. HARPER: So do you think the
11 interstitial CGMs are -- are going to be accurate
12 enough for this use, or do you think that you need a
13 whole blood CGM?

14 DR. FURNARY: I personally believe we
15 probably need a whole blood CGM but because the
16 current interstitial devices that are out there have
17 been out there for what, Irl? Six years now?

18 DR. HIRSCH: Mmm. . .almost five.

19 DR. FURNARY: Five? That's pretty good for
20 a surgeon -- I was close.

21 DR. HIRSCH: You're not a typical surgeon,
22 Tony.

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1 DR. FURNARY: I'm going to park in the bay.

2 [Laughter.] What was the question? [Laughter.]

3 That's a typical surgeon.

4 DR. HIRSCH: Yeah -- yeah, annual --

5 DR. FURNARY: No, interstitial device --

6 and we haven't used them. And I'm taking up too much
7 time because I'm not on the panel.

8 DR. BERGENSTAL: Irl, I mean I briefly
9 showed you a little bit of data today to say there are
10 some intravenous continuous monitors that I think are
11 early but starting to show that it's possible to do
12 this. I mean, those 19 patients were exposed to -- I
13 think it was 150 different drugs of all types from L-
14 Dopa to Acetaminophen, to -- and they still held up
15 with very good MARDs. So, I mean it's early, it's
16 research. But that's where I think we are headed. To
17 Tony's point that we can get a continuous monitor in
18 the ICU -- don't think we need that on the floor --

19 DR. HIRSCH: Yeah. And I agree with you
20 because we're dealing with intravascular and not
21 interstitial fluid where you're going to have even
22 more changes in lag and problems and hypotensive,

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1 hemodynamically unstable patient if you are actually
2 in the vessel. The surgeon or the pediatrician?

3 DR. FURNARY: Well, he said I like to hear
4 myself talk, so since surgeons have big egos, I'll
5 just sit down.

6 DR. HIRSCH: Okay. Go ahead, next -- next
7 speaker.

8 DR. GINSBERG: I just wanted to make a
9 comment. A couple of years ago, I presented a paper at
10 the diabetes acknowledgment society talking about
11 partial duplicates, which -- since CGM is a frequent
12 measurement, the values that it gets every five
13 minutes are not independent. That, within reasonable
14 limits, patients don't change blood glucoses very
15 quickly. That if a patient blood glucose is 100 now,
16 it is not going to be 200 -- most of the time -- five
17 minutes from now. In particular, when it's on a
18 continuous infusion. And so therefore, if I get a
19 value now which has an error of 15 percent. And I get
20 another value five minutes from now which has an error
21 of 15 percent. If you assume they're complete
22 duplicates, which they are not, then the error of

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1 those two measurements together is only 11 percent.
2 If they get another measurement five minutes from
3 then, then the error goes down to about nine percent.
4 And after not very many measurements, my error is no
5 longer 15 percent, my error is now six, or seven, or
6 eight percent. Plus I'm getting a trend out there now
7 with the understanding that there are all sorts of
8 problems that you just limited, in terms of
9 hypertension and so on, for continuous systems for
10 patients in which they do work. I'm not sure the lag
11 is all that terrible. A 15 minute lag under these
12 types of circumstances is probably not as bad as we're
13 seeing anyway. And at least it's something to think
14 about in terms of how we use these things. I just
15 wanted to point out the duplicate problem.

16 DR. HIRSCH: Good point. Good point.

17 Anybody else? Next speak --

18 DR. WHITE: Neil White from Pediatrics at
19 Washington University. First of all, I want to -- I
20 want to say that I'm very pleased and compliment Dr.
21 Furnary and the other woman here from the Burn Center
22 on how good a job they can do, but I think what we

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1 have to try to figure out is what kind of technology
2 we need so that all the rest of us can come close to
3 doing such a good job. Whatever that job needs to be,
4 whether it's 80 to 110, or 110 to 140, or whatever
5 that is. I'm not going to weigh in there because I
6 have no knowledge in this area other than what I heard
7 people say. But we probably need technology that
8 would enable me, if I were in that boat, to do the
9 same thing that Dr. Furnary can do, which I don't
10 think we can do at most hospitals.

11 DR. HIRSCH: But -- but one comment to
12 that, Neil. One of the things that Dr. Furnary said
13 wasn't just the issue of the technology; it's the
14 frequency of testing.

15 DR. WHITE: Well, I think I agree with the
16 point that the more frequent the testing, assuming
17 it's reliable, the closer we'll be -- we'll be able to
18 do this, okay? Continuous glucose monitoring is
19 probably the way to go, but I would have doubts that
20 continuous glucose monitoring of interstitial fluid in
21 the ICU setting would be a way to go. If there's
22 continuous glucose monitoring in the vascular setting,

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1 I think that would be a big step in favor of doing
2 this. And I know there are things being worked on. I
3 mean that would probably be a way to go in that
4 setting. Totally different -- just like meters are
5 totally different -- for the setting of the average
6 diabetic walking around on the street.

7 DR. HIRSCH: I guess my only point, and I
8 don't know about the IDC in Minneapolis or anywhere
9 else, but the number one complaint that I hear about
10 especially when we start talking about I.V. insulin on
11 the floors, or even sub-Q insulin in somebody on MDI
12 is that the nurses tell us that they don't have the
13 time for the minimal amount of testing we do now.
14 Over and over and over again, that is the complaint
15 because the nurse to patient ratio isn't enough to
16 keep that. And that's just the complaint. We've been
17 able to deal with that somewhat at my institution, but
18 it's tough.

19 DR. WHITE: What your institution's able to
20 do is admirable. And as you know, I have a lot of
21 experience in the past with I.V. infusions of insulin.
22 But if I try to do what you do at your medical center

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1 at my pediatric hospital, they string me up every
2 other week when I bring it up.

3 DR. HIRSCH: Go ahead. Do you have any
4 comments?

5 DR. MESOTTEN: I mean I completely agree
6 with you. I mean, it's maybe true that Dr. Furnary
7 can do tight glycemic control with point of care blood
8 glucose meters when you measure every 30 minutes. But
9 I mean there's ample literature out there saying that
10 -- measuring at least every hour is already very hard
11 for the nurses, and it increased too much of the work
12 load. So, I think we have to improve something about
13 the technology so that we can go to measurements less
14 than one hour and talking about continuous monitoring
15 is not there at the moment, and they still have to
16 prove they have value in the clinical setting. So in
17 the meantime, we have to do something. And there I
18 don't agree. I mean you can say that you measure
19 every 30 minutes, but that's -- in most centers, in
20 Europe and U.S.A., wherever you are, is impossible and
21 definitely not in medium care or the channel ward
22 (ph).

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1 DR. HIRSCH: Thank you. Yes?

2 MS. KOLLER: Beth Koller from Medicare. I
3 have a question that's more broadly directed toward
4 data sources and probably relates to something that
5 Dr. Beaston or Dr. Harper can answer. At our agency,
6 we frequently have sponsors come in to present about
7 their products. The data maybe -- the sponsor may
8 also be a vendor for that product for durable medical
9 equipment. And the information may be derived through
10 those vending activities. The vendor supplies that
11 informa - - supplies the product to the patient, but
12 the data stream basically appears to be through the
13 sponsor plus or minus the durable medical equipment
14 vendor. And we have some questions as to whether the
15 FDA would accept data if in fact the data were not
16 obtained having gone through an IRB protocol, and if
17 there was no patient consent. And there was not a
18 clear protocol.

19 DR. HARPER: Our regulations require that
20 studies done on human subjects be done under IRB and
21 under informed consent.

22 MS. KOLLER: That's not necessarily the

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1 kinds of data that we see. I point that out to show
2 the differences between the two agencies.

3 DR. FURNARY: I want to come back to a
4 point that Richard said and that was that, you know,
5 this is something that we do in the ICU. I don't
6 disag -- I disagree with that. Glycemic control is
7 not just for patients in the ICU. And our data, as
8 well as the Leuven data, and Irl's data -- there's a
9 number of -- there's a lot of data out there that
10 shows that the length of time that you're
11 hyperglycemic, the length of time is what impacts
12 outcomes. It's not just the target level; it's how
13 long you're there. Same with hypoglycemia -- it's not
14 just how low you go, it's how long you're there. And
15 to limit glycemic control to a patient population that
16 resides in the intensive care unit is to say, "It
17 doesn't matter out there." It would be like giving
18 less than a full course of antibiotics. It's the same
19 thing. We didn't -- antibiotics don't improve
20 infection if you just give them in the ICU -- you give
21 them after the patient leaves the ICU. Because
22 there's a duration of care that matters. Just like

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1 that, the duration of care impacts the outcome and
2 glycemic control. So I believe that glycemic control
3 is something that should be afforded all the patients,
4 including patients on the floor, and that also speaks
5 to why we need a very accurate CGM monitor on the
6 floor so that the nurses aren't continually doing this
7 on the floor, and it doesn't take up all the nursing
8 time. So you asked -- it comes back to the question
9 what do you think we need? That's what I think we
10 need.

11 DR. BERGENSTAL: All right. And let me
12 just respond, because I hope I didn't imply that --
13 when I was saying -- yeah, I think we definitely need
14 control on the floor. The question is whether it is
15 80 to 110, and again I'm coming back to it's just the
16 personnel and the staffing at the moment doesn't make
17 80 to 110 practical on the floor. We probably are as
18 aggressive as anyplace with the -- what we call our
19 complete insulin orders and the triple orders on the
20 floor with frequent monitoring, but that we can get --
21 we can get 110 to 150, sort of, on the floor.

22 DR. FURNARY: Yeah, thank you Richard. I

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1 just wanted to be sure that FDA heard that. That this
2 is -- to me, this is not an ICU ther -- ICU only
3 therapy. And I think --

4 DR. BERGENSTAL: But that's where that term
5 gets a little -- TGC is sort. . .

6 DR. FURNARY: It's glycemic control.

7 DR. BERGENSTAL: I -- yeah, I'm for glyc --

8 DR. FURNARY: It's glycemic control.

9 Whether you call it tight or strict or intensive.

10 DR. HIRSCH: You don't want to just call it
11 GC, Tony, that's something else.

12 DR. FURNARY: Yeah, I don't -- we know what
13 that is.

14 DR. HIRSCH: Yes. Okay. Go ahead.

15 MS. COOPER: Hi. My name is Emily Cooper.

16 I'm a clinical nurse specialist at York Hospital in
17 York, Pennsylvania, and we're a small community
18 hospital -- about 550 beds. And I just wanted to give
19 you the perspective of, you know, outside of a
20 university setting. We use Portland protocol. I work
21 with cardio-thoracic surgery patients, and I have to
22 tell you that our biggest barrier to getting tight

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1 control with that protocol is our glucose meter. It
2 has a lower hematocrit threshold of 25 percent, and
3 with the permissive anemia we have with those
4 patients, we have a lot of patients that are below
5 that threshold. And because of the litigation issues
6 described this morning, our institution mandates that
7 if their hematocrit is less than 25 percent, we have
8 to send a whole blood glucose to the lab. So you can
9 only imagine the chaos that ensues, and when they're
10 in the intensive care unit they at least have an A-
11 line that the nurses can draw off of, but still with
12 the lab turnaround time we're not getting --

13 DR. HIRSCH: What is the lab turnaround?

14 MS. COOPER: If they're in the unit, we can
15 maybe get it in five or ten minutes for a whole blood
16 glucose, but then like Dr. Furnary said, once they get
17 out to the floor and they no longer have a line, then
18 it's a phlebotomy stick. And we can't run the insulin
19 drips on the floor because of that. And these poor
20 patients are getting stuck eight times a day --
21 phlebotomy sticks just so we can measure their blood
22 glucoses.

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1 DR. HIRSCH: So --

2 MS. COOPER: So we obviously need something
3 different --

4 DR. HIRSCH: Yeah, so --

5 MS. COOPER: I have to say too, real
6 quickly, our institution -- you know, there's
7 obviously other technologies out there, these lovely
8 four-channel glucometers, but because our current
9 glucometers, you know, on face value, meet ISO
10 criteria, there's no incentive to get new technologies
11 -- especially in this economy.

12 DR. HIRSCH: So what you are really saying
13 -- to answer the broader question, "What technology do
14 we need?" We need better glucose meters that are
15 accurate in terms of measuring people's glucose who
16 are severely anemic. That's a huge problem. We've
17 heard that several times today.

18 MS. COOPER: Yes.

19 DR. HIRSCH: Okay. Thank you for your
20 comments.

21 MS. COOPER: Thank you.

22 DR. HIRSCH: We are at -- almost nearing

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1 the end of the session. I get the one minute card
2 here hitting me in the face. Does anybody have any
3 concluding comments that they want to make before we
4 do end the session? I want to -- Patricia, I want to
5 get back to your comment just for a moment about what
6 would be acceptable in terms of the more accurate
7 device, in terms of the amount of time. Because I
8 personally don't know the right answer. I think
9 everybody in the room would like to see more accurate
10 readings in the hospital, both in the ICU and to
11 Tony's point, on the floor. Ideally, we like it to be
12 cheap. We wouldn't like it to take away all the money
13 we have. And by the same token we like it to be fast.
14 But it's a -- you know, as we heard just now from this
15 nurse from Pennsylvania, there is a real problem even
16 dealing with sub-Q insulin when you have to wait an
17 hour at the best, maybe even longer on the floor, if
18 you're dealing with somebody on multiple daily
19 injections, and the meal is there and you have all the
20 normal things that happen. Maybe the patient feels
21 hypoglycemic but isn't. But the nurse can't use the
22 glucose meter at the bedside because of hypoglycemia.

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1 I mean, there's a lot of issues here that we did not
2 come to a consensus on today, and I'm not surprised
3 with that. I personally don't have an answer for you,
4 but I think, to me anyway, that's the most provocative
5 question of this past hour because I really don't know
6 where to even start. Because I think the real answer
7 is often going to be with the administrators and not
8 with clinicians like myself. So, any final comments
9 from anybody before we end this provocative
10 discussion? No? If that's being -- one last comment
11 here.

12 MR. TORJMAN: Marc Torjman. I'm at Cooper
13 University Hospital. There's one thought that I had
14 and this is from the hospital side, having done a lot
15 of these measurements in ICU patients. I work also
16 with Dr. Phil Dallenger (ph), and I have to say that
17 there are a lot of good meters out there. Good
18 glucometers in major institutions as opposed to maybe
19 small community hospitals, the laboratory directors
20 know about those meters. They're well below the ten
21 percent MARD. I've tested them myself. They perform
22 well compared to a YSI. So, I think that the

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1 frequency of measurement when you're giving I.V.
2 insulin therapy is critical. If you are limiting
3 yourself to one hour measurements, unfortunately
4 that's -- you know what the limitations are because
5 it's an FTE problem. At Cooper, for example, the way
6 Dr. Dallenger does it is when somebody goes on an
7 insulin infusion, the task is helped by a technician.
8 The nurse -- the glucose measurements are taken over
9 by this FTE person that will only do blood glucose
10 measurements. Not everybody can do that, so that's a
11 limitation. But I think the point I'm making here is
12 that I've checked the AccuCheck inform system, the
13 HemoCue when I was at Jefferson for 20 years -- worked
14 with those devices. They're below five percent MARD.
15 So if you can afford those devices, they're out there.
16 The accuracy is out there. The question is, what
17 protocol are you going to follow if you're going to go
18 80 to 110? A one-hour measurement frequency is just
19 not going to do it and you're going to run the risk of
20 hypoglycemia. So if you push your protocol up to the
21 140 -- 140 to 180, then perhaps the accuracy becomes
22 less of an issue and you have to really balance out

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1 the frequency. So that's what I wanted say.

2 DR. HIRSCH: Thank you very much. Okay,
3 with that, I think we will end this session and I
4 thank you all for your attention. We'll move on to
5 the next session.

6 DR. HARPER: So I'd like to thank all the
7 presenters and moderator for Session 3 for a great
8 session. I think -- I know I learned a lot and I hope
9 that you all did too. It looks like we still have a
10 little work to do in terms of the clinical community
11 to get together so that we can figure out some of
12 these questions, but it sounds like we are well on our
13 way to that. So now it's my pleasure to introduce the
14 next speaker. Ellen Ullman has been a passionate and
15 tireless proponent for diabetes advocacy since 1989
16 when her 22-year old son was diagnosed with Type I
17 diabetes, and she's going to talk to us today about
18 consumer use of glucose meters and also how consumers
19 choose meters. So, welcome Ellen.

20 MS. ULLMAN: Well, I see not too many
21 people have left for the airport, so I have more
22 people to address than I thought. I just wanted to

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1 say because it did say in the program that I work for
2 Close Concerns that what I'm presenting today is
3 completely my personal opinion and really is nothing -
4 - is not representative of Close Concerns. So I ran a
5 little survey on the internet. I had about 500 people
6 who completed it, and this is the breakdown of who
7 responded. More women than men, 36 percent had Type I
8 diabetes themselves, 48 percent had a child with Type
9 I, 13 percent had Type II, 3.2 percent had LOTA (ph),
10 and then there were just a few with different aspects
11 -- other areas of diabetes. And 90 percent of the
12 people do have insurance coverage. So if you see the
13 people that I surveyed are actually checking blood
14 sugar quite often. The blue is five to eight times per
15 day, and that's 42 percent, and the goldish color is 8
16 to 12 times per day. So people are very
17 conscientious. Two to four times per day, 16.6
18 percent. It was mentioned by Mr.

19 Rollins that for Medicare patients it's
20 required that they get training in how to use their
21 meter. So when asked, "Have you been instructed by a
22 healthcare provider how to use your meter?" 63 percent

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1 said yes and 36 percent said no. So, some people are
2 going home and figuring it out on their own. Control
3 solution -- in my opinion it should be in the box so
4 consumers can choose it because every time you use
5 control solution to compare to see how accurate your
6 meter's functioning, it's really only good as that
7 vial of strips that you're testing. It's not the
8 meter accuracy -- it's that vial of strips. Asking
9 people on average how often they use control solution
10 -- 41 percent say never, 14 percent onetime per year,
11 ten percent four times per year, nine percent two
12 times per year, and then it goes down and 3.3 percent
13 said, "I am not familiar with control solution." I
14 think that when we used to get it on our meters,
15 myself personally, we did use it more often. But now
16 we don't even get it, and we don't have it. It said
17 in this ADA consumer guide that it cost \$15 for a
18 bottle of control solution and once you open it, it's
19 only good for 30 days. So, that's a considerable
20 expense for the consumer. So here is a tweet from
21 Twitter: "5 a.m. low. The meter said 79. No way!
22 Help me discovery expired test strips -- lovely.

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1 Control solution had them in range, but in the upper
2 range though." So some people out there are using it.
3 Coding the meter -- have you ever forgotten to change
4 the code on your meter? Well, if people are checking
5 their blood sugar 12 times per day, it's pretty likely
6 that they are going to forget on occasion to code, so
7 57 percent said yes they have and 31 percent said no.
8 And I guess the others have no code meters. Using
9 strips beyond the expiration date. Have you ever
10 knowingly used blood glucose test strips beyond the
11 expiration date? And almost 20 percent said yes. And
12 I think that we're going to see a lot of more of this
13 -- not that industry can really do anything about it,
14 but given that people are less insured, or
15 underinsured, that they're going to use the strips
16 that they have. And this is a quote that I got in an
17 e-mail from a friend whose son does not have
18 insurance. "If he's using strips, they are outdated
19 ones." Frequency of cleaning skin -- well, this was
20 what was mentioned. How few people actually clean. So
21 20 percent said that they check -- that they clean
22 every time. And almost 20 percent said very often,

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1 and 11 percent said often, and 6.5 percent said never.
2 So I think, actually, it may be more frequent that we
3 imagined -- at least among this population. And as
4 far as temperature, humidity, high and low -- I asked
5 if they keep a meter and strips in the car. 34
6 percent do, so then obviously these are exposed to
7 extreme temperatures. 62 percent of the people do not
8 know the temperature range of the meter, and 33
9 percent do not know the high and low range of the
10 meter. I think it would be really helpful, instead of
11 saying high, flashed 500+, or -20, or less than 20, or
12 less than 30 -- whatever it is that your meter has so
13 that people can make more of an accurate dose
14 decision. Because if they don't know that their meter
15 goes to 500 or 600, they may be overdosing assuming
16 that it's too -- it's even higher than it is. And I'm
17 not going to go through all the other interferences
18 that were already covered. So how many times do
19 people have to use more than one strip? 45 percent of
20 the patients said they sometimes use more than one
21 strip because they do not trust the accuracy of the
22 result.

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1 And again, I just chose some random Tweets:
2 "Test strips for my glucose meter -- you are
3 expensive, that's why you are constantly wrong, making
4 me use more of you than I need." Well, I have to say
5 that I do hear parents very often, and patients very
6 often are retesting. They don't believe it, and
7 although we discuss -- it's been mentioned that they
8 are simply outliers and they're not that frequent,
9 more frequently that you imagine we get results that
10 just don't make sense. And then when we retest, we
11 get a result that seems a little more reasonable. And
12 then here's another person -- it took her five test
13 strips to get enough blood. These are the other
14 factors that we've already discussed. I'm just going
15 to move along. And then I come to how consumers
16 choose meters, or is it really should I ask them how
17 are meters chosen for you? Because, not everybody has
18 a choice today. So the first thing and how do we
19 choose -- the ADA is clearly a reliable source. We
20 get this guide every year -- 2010 -- before they go
21 into comparing, we have a little article on accuracy.
22 How do you determine -- how do you know your meter is

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1 accurate? And in this little article, it says that
2 they are now required to an international standard of
3 within 20 percent margin of error and every time you
4 open a box of strips that you should check with
5 control solution. But, as I said, \$15 for control
6 solution that's going to expire in 30 days. There's a
7 disincentive to buy it on your own. That's why I would
8 advocate that it goes in the box. But they do manage
9 to name the criteria to choose from to compare meter
10 name, the blood sample size, what kind of battery,
11 etc. But there's absolutely nothing that compares
12 accuracy. And there is no way for an informed
13 consumer today to determine how accurate their meter
14 is. And we even heard that FDA doesn't permit them to
15 make claims because as long as it's within the
16 standard, that's the criteria they have to meet. But
17 I think, as a consumer, I want to be able to compare
18 from one meter to another and simple control solution
19 is not going to tell me that my meter is more accurate
20 than someone else's. So my feeling is there should be
21 standards for comparison, especially for accuracy.
22 People have perceived that they're accurate. A lot of

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1 people if you just ask -- I ask my mother, she's 82.
2 She thought it was within two percent. Surely, if FDA
3 approves it, it must be an accurate meter. And I
4 think that's probably your very typical Type II older
5 population who believes our government cares about it
6 - - and I do believe FDA cares -- but I think that we
7 just don't know what the laws are and what the rules
8 are. Co-pay is another thing people consider. How
9 much am I going to have to pay? Some insurance
10 companies are saying, Well, you can have any meter
11 that you want, but for this meter, you're only going
12 to have a \$10 co-pay. For the other, you're going to
13 have a \$50 co-pay. Well, when you're testing 12 times
14 a day, it's going to make a big difference. Other
15 things that people decide, How can I get a free one?
16 They're everywhere. Medicaid and some insurance do
17 not give any options whatsoever. This is the meter
18 you're getting; this is the meter you're going to use.
19 Take it or leave it, or buy your own. And then no
20 insurance people -- they're going for the cheapest
21 strips. So here's one -- this person actually lives
22 in my area. He says, I'm a little worried about this

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1 meter. I'm not going to mention it. It's not working
2 properly. I don't have control solution. I need to
3 go get a free meter somewhere, because he's looking
4 for yet another free meter. It's a problem. Other
5 things that they do to choose meters -- obviously, if
6 you're physically challenged, it has to be an ease of
7 use -- how to get the strips from the container out of
8 the container. Sometimes they open the container, all
9 the strips fall on the floor because for whatever
10 reason it was so hard to open that container, it snaps
11 and it falls down. How to get the strips into the
12 meter, getting the blood onto the strip, large display
13 backlight and, of course, for visually impaired, they
14 need a voice activated, so these are other
15 considerations that people take into account when
16 choosing a meter. So when asked where do you obtain
17 the glucose meter most frequently used in your home,
18 almost 30 percent from healthcare provider. And this
19 was interesting, almost 30 percent from your insulin
20 pump company. And 22 percent from your local
21 pharmacy, and then free or your DME company, etc. The
22 insulin pump and CGM users don't really choose which

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1 meter they want -- they need to use the meter that's
2 going to beam up the information either into their
3 pump or the specific one that's going to calibrate
4 their CGM, and that's what they're using. And all --
5 of course it's not approved by F -- it's not approved,
6 it's not indicated, but I can tell you that dose
7 decisions are being made by CGM users and they are
8 calibrating with the meters that in my opinion are not
9 sufficiently accurate today. When asked to rank what
10 are the most important factors -- I had listed maybe
11 15 or 20 -- I will give Arleen a copy of the survey.
12 What are the most important factors when choosing a
13 meter? Number one was accuracy -- 77.5 percent.
14 Number two -- blood sample size, three -- cost of test
15 strips. They could rank all of the different things
16 as either most important, important, least important,
17 not applicable. Perceived accuracy -- so I asked --
18 and this was not a well-worded question. I now
19 understand better that the less than 75 has to have a
20 different parameter. So I said according to FDA
21 requirements, home blood glucose meters must be within
22 what percent of actual blood glucose value from a lab,

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1 and if you're unsure, please choose your best guess.
2 And to me it was surprising -- 46.1 percent believed
3 current accuracy required is between one and ten
4 percent. And then you've got, you know, you're more
5 knowledgeable people that said 20 percent because they
6 knew and then a little over five percent, six percent
7 said higher. And so I'm here really representing all
8 of the people out there, and it's a daunting task,
9 that use home blood glucose meters every day.
10 Numerous times a day, their lives depend upon it.
11 They're making dose decisions for insulin for
12 themselves, for their children. Here's some quotes,
13 "I'd love to find a meter that had closer error
14 tolerances -- accuracy less than one to two percent."
15 This person says, "As everyone knows, meters are
16 allowed to be twenty percent off. It's unacceptable.
17 I have four meters lined up to do a test using the
18 same blood drop. Each meter shows a different number
19 -- 80, 90, 100, 110. That could still be a range of
20 blood sugars from 60 to 120, so which number is it?
21 And if anything needs to change, it's the accuracy of
22 the meter." And then this person asked, "What does a

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1 person with Type I diabetes do when they have no faith
2 in their glucose meter?" And it's tough -- it's tough
3 when you can't afford to buy another test strip. You
4 can't afford to repeat the test. You know that you
5 don't feel like what it says, but you've got to make a
6 decision. Here's another one, "No way is 20 percent
7 variance good enough. That the FDA does not make the
8 band tighter is being irresponsible for my child's
9 health. We dose based on that number. She's so
10 insulin sensitive; it would make a huge difference to
11 control. They can require meter makers to do better."
12 And another -- they feel that it's appalling and
13 there's no reason why it can't be within one percent.
14 Well, I'm not an engineer, I'm not industry, I'm not
15 here to say what can and cannot be achieved. I'm just
16 here to share what people feel. So regarding
17 yesterday's discussion. Consumers are the end user,
18 regardless of the setting. Hospital, office, school,
19 soccer field, home, nursing homes, daycare -- we're
20 all the end users. Yes, we need accuracy in the
21 hospital to protect people from hypoglycemia. We need
22 the same thing at home. It's really not that much

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1 different. When meters are even more off in the high
2 end, we're giving extra insulin that should not be
3 dosed. But we're basing it on these meters that do
4 have that error. Labeling -- we have no way as a
5 consumer to know what accuracy there is in any meter
6 that we choose. We need to have 1) education and 2)
7 labeling. We need to know how we can make an informed
8 decision. Shipping and storage -- in my opinion,
9 there should be guidelines as far as that goes. We
10 don't know how long they're sitting in the heat, we
11 don't know what they're exposed to, and it's most
12 likely that people are not going to be using the
13 control solution every time. Tight glycemic control -
14 - I can tell you from a parent's perspective, they are
15 always trying to get it to 80 to 120. It's almost an
16 obsession -- parents sometimes check blood sugar two
17 times in the night, in addition to all the times
18 during the day. It is considered best practices.
19 Women who are pregnant have an extremely tight
20 control. And for them to be off, it's even more
21 dangerous. And the outliers do happen, and each
22 outlier is a potential disaster. At least for a

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1 little child and for anyone taking insulin, if they
2 are not going to recheck, or double check, or triple
3 check. So the outliers cannot be dismissed. Usability
4 and convenience -- it just absolutely cannot trump
5 accuracy. Accuracy has got to be primary, it has to
6 be paramount. It must be improved. Regarding the
7 suggestion that there should be different meters for
8 Type IIs on oral medication versus Type II on insulin
9 versus Type I who's on insulin, I think in theory it
10 really does make interesting and good sense. However,
11 in reality -- well, actually I think everybody
12 deserves accuracy. But in reality, what's going to
13 happen is managed care is going to give people the
14 least accurate, the cheapest meter available. And
15 that's what's going to happen regardless of the
16 indication. I also don't think that anybody should
17 have to have less -- why should anyone be exposed to
18 less accuracy? Why should anyone be exposed to
19 possibility making a dose that would be wrong, even if
20 it's oral medication? And I feel very strongly -- we
21 have to phase out the inaccurate lower standards.
22 People can and will learn to use new meters. People

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1 can and do learn new technology every single day. I
2 thought that Marc's graph -- ten percent was
3 absolutely compelling. The difference between ten
4 percent and 15 percent, or the difference between ten
5 percent and 20 percent was extraordinary. And even
6 between ten and 15 percent was huge. So my feeling is
7 if there are meters capable of achieving accuracy
8 within ten percent today, that should become the new
9 standard. And on behalf of all patients who depend on
10 blood glucose meters, I thank you. I thank you for
11 thinking of them as human beings, not just people that
12 -- not just a number in a study, not just a number and
13 how many strips you can sell. These are human beings.
14 And I did have a video but it won't play, of an
15 adorable three year old testing her own blood sugar.
16 She checks, and then she doesn't get enough blood.
17 And then she checks again and she has two little
18 holes. And then she puts the blood on the strip and
19 then the meter slips out of her hand, but she's so
20 proud of herself because she's done it herself. And
21 these are the people who are testing every day.

22 DR. HARPER: Thank you, Ellen. That was

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1 very compelling, and we have time for a few questions
2 for you.

3 MS. ULLMAN: Thanks.

4 MS. PINKOS: You said two things that I'm
5 interested in hearing your opinion on. One, that
6 people do -- are interested in the accuracy of the
7 meter. Do you have any ideas on how would be an
8 effective way of giving that information to consumers
9 so they would have the information available to make
10 an informed decision? And maybe even it might be
11 something for physicians. And the als -- the other
12 thing is do you have any ideas on what is an effective
13 way of communicating the limitations of meters to home
14 users?

15 MS. ULLMAN: Oh, okay. The first question.
16 Well, certainly I would love for ADA to include it in
17 their annual consumer report of comparisons so that
18 people could actually compare and there -- and this is
19 something that people likely do refer to, at least
20 once a year. And why -- on the box. I think we have
21 to set standards so at least we have comparison
22 standards and Dr. Ginsberg, you certainly showed how

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1 we can put it right there on the box, on the vial.

2 And I'm sorry, the other question?

3 MS. PINKOS: What's a good way of
4 communicating the limitations to users? We kind of
5 heard that people aren't aware of the limitations. Is
6 there any ideas you have?

7 MS. ULLMAN: Certainly not in the
8 microscopic font in the patient inserts. I think it
9 has to be in any user quick reference guide -- large,
10 colorful. On the box, of course, do not use if you're
11 anemic. You have to use terms that people will be
12 familiar with. They're not going to know their
13 hematocrit level. But there are people out there
14 anemic. Ten percent of the people with Type I
15 diabetes -- up to ten percent have celiac. A lot of
16 those people are anemic too -- many of them are
17 undiagnosed with celiac, so we need to use
18 terminology. The other thing that would be really
19 great if we could register each meter, so that when
20 there's a recall, people get an instant e-mail notice.

21 MR. MELKER: Rich Melker from the University
22 of Florida. First of all, thank you for grounding us

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1 back down to the reality of what the people in the
2 real world have to deal with. I mentioned glucose
3 control solutions yesterday. I did a survey several
4 years ago of some of the major pharmaceutical chains -
5 - pharmacy chains, excuse me. And one chain sold
6 300,000 glucose meters in a year and less than two
7 dozen vials of control solution. So most diabetics
8 have no idea what to do with glucose control
9 solutions, and as you know the manufacturers went from
10 having a high and a low to have a normal and they
11 don't even include it sometimes anymore. The answer
12 to that issue is very simple. The manufacturers have
13 to figure out a way of, when you put a strip in a
14 meter, if the strip isn't good the meter doesn't use
15 it. There is no way that the average diabetic is
16 going to understand how to use glucose control
17 solutions. The big problem is when somebody leaves
18 their meter in a car in Florida in the summertime.
19 They've probably ruined all the strips and they're
20 going to get wrong information from those strips if
21 they use them, but you have the situation where,
22 unlike me where I do a lot of research and I get a lot

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1 of free strips and I can stick myself four or five
2 times and look at different meters and look at
3 multiple strips, the average person has a vial which
4 they left in the car and they're on the second strip
5 and the strips are no good. To throw away 48, 47 more
6 strips is a huge problem for them because they are not
7 going to get anymore unless they pay for them out of
8 pocket, and just to ground people in reality, the
9 major manufacturers have all kept the price of their
10 strips to the very same price and on average, they're
11 about 75 cents a strip. So, the other last thing I
12 want to say is they talk about strips only using 0.3
13 microliters of a sample, but if you have a little drop
14 of blood on your finger, and you don't line it up just
15 right, you just wasted a strip. So it may be .3
16 microliters that it takes to do the sample, but if you
17 don't get a nice drop of blood on your finger, you got
18 about a 50/50 change of that ever going into the
19 strips. I've also encountered several instances where
20 you open a vial and no matter what you do, the strips
21 don't actually -- the capillary action or the lateral
22 flow, whatever you call it, doesn't actually pull the

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1 blood into the strips. And since I understand how the
2 strips work, I'll go and take out my loop and I'll
3 look at the strips and find out that the little hole
4 that is supposed to be there that allows the air to
5 escape when the blood goes in wasn't punched in the
6 right place. So, you've got a lot of strips, a lot --
7 L-O-T -- meaning a whole lot of strips that the
8 company probably made wherein the manufacturing
9 process, they missed the spot. And I can tell you
10 over the last 15 years of testing five to seven times
11 a day at least, I've encountered this problem on
12 numerous occasions. I've also encountered the outlier
13 situation on numerous occasions, where one strip in a
14 whole vial is completely different than the other
15 ones. Because I'll go take a couple more strips, and
16 then I'll take some strips from a new vial to test
17 them against those. The other thing that nobody has
18 mentioned here is that most -- well, I shouldn't say
19 most -- a lot of diabetics have more than one meter.
20 They keep one at home and they keep one when they
21 travel. When I travel, I always take two, just in
22 case I have a problem with one or it decides to

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1 finally fail -- which they do. So, unless they're
2 using all the strips frequently for both of those
3 meters, some of those strips are going to become
4 outdated. These are the realities -- the real things
5 that people that have diabetes deal with everyday.
6 It's really nice -- and I'm from an academic medical
7 center, for the academicians to come up here and talk
8 about how in very controlled environments what they're
9 capable of doing. Most diabetics -- first of all, I'll
10 just give one last anecdote -- I walk into my hospital
11 as a patient and I'm on a surgery service and they
12 tell me their putting me on a sliding scale, so I sit
13 the surgical resident down and I explain to him about
14 Lantus and Humalog and I'm going to test my own
15 glucose and I'm going to give myself my own insulin
16 unless they get somebody on the floor who understands
17 how to do it. I call my diabetes colleagues, they
18 come on the floor and they educate the surgeons for my
19 benefit, and the day I leave, it never gets done
20 again. So, the reality is we have all kinds -- we
21 have 5,000 hospitals in the United States. Most of
22 them do not do anything that you've heard today.

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1 They're completely different. They're using sliding
2 scales, they can't test once an hour, I can go on and
3 on and on. They don't even know how to calibrate the
4 meters that they have on the floors. We've published
5 some data on the effects of temperature and humidity
6 and these are the real world issues and these are why
7 people are overdosing on insulin and getting
8 hypoglycemic or walking around with sugars of 240.
9 That's the reality. It's really nice to hear the
10 other stuff, but glucose control systems have to
11 disappear. The manufacturers have to figure out a way
12 that if a strip is bad, you put it in the meter, and
13 it tells you they're bad, and you can send them back
14 and get new strips if they're fault of the
15 manufacturer.

16 DR. HARPER: Thank you, we actually --

17 MS. ULLMAN: So I wanted to ask you --

18 DR. HARPER: We only have time for one
19 additional brief question. If we could hear from
20 someone, perhaps, that we haven't heard from yet.

21 MS. LOON: Thank you. Judy Loon --

22 DR. HARPER: First of all, Ellen, did you

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1 want to respond to that?

2 MS. ULLMAN: Well, I just wanted to know if
3 when you discovered that the air hole on the other
4 side of the strip was not pierced properly, did you
5 report it to FDA, or did you report it to the
6 manufacturer, or what did you do? Because this is
7 what we need to educate the consumers, too. What do
8 you do when you discover --

9 DR. HARPER: Yeah, briefly.

10 MR. MELKER: Real quickly -- I used to
11 report a lot of stuff and it doesn't -- nobody cares.
12 It goes into a database, nobody looks at the database.
13 I stopped doing it. I just take out a new vial of
14 test strips.

15 DR. HARPER: We actually do care, and when
16 you report through the -- when you report through the
17 website that I gave in my slides, they actually -- we
18 read and we actually contact the reporters as well,
19 because we really do want to understand these issues.

20 MR. MELKER: [Off mic.]

21 DR. HARPER: You can report directly to us,
22 actually. I encourage that.

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1 DR. LOON: Judy Loon. I'm from Hilton Head
2 in private practice. I also work with the veterans in
3 Savannah at the outpatient clinic. I think it's good
4 that we hear what patients and caregivers are really
5 thinking about all of this, so that's a nice survey.
6 But again, when you even look at that survey, it --
7 you know, anyone who responds to a survey is more
8 serious about their diabetes and you said they all
9 have insurance. So I shudder to think what my
10 patients in Savannah look like. But I share his whole
11 thing about the control solution. Because it is a
12 problem. If you look at Medicare, they will only give
13 you one bottle for six months. So he opens the
14 bottle, it's no good after 30 days, so five months
15 they have no control solution. In the VA, we just
16 changed meters and we have trouble enough to try and
17 get the simplest meter and teaching to their level.
18 So they decided, in their wisdom, to take the control
19 solution out because that would be a problem teaching.
20 So they get no control solution. But I think one
21 thing that we haven't talked a lot about these two
22 days is mail order houses. And that is how patients

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1 get a lot of their machines. And there is no
2 education, trust me. They will send the cheapest
3 meter, the cheapest strip, because their mark- up on
4 the cost of the strip -- they want to send you the
5 thing they're going to make the most money with. So
6 the patient gets no education. And they will just
7 call the patients -- they get their names off of
8 rosters, and they will say, "Have you had a meter in
9 three to five years? Well, let's send you one." And
10 they get whatever the company sends. Physicians don't
11 have time to look and see what that is. So that to me
12 is a real concern. And, you know, you're mailing
13 these strips out. Go to a post office in Savannah in
14 the back room. It's as hot as Florida, trust me. So,
15 you know, these strips cannot be good. But this is,
16 in reality, what's happening. And when you try to
17 report anything -- I actually had one of the big
18 companies -- on two patients, they sent, to be signed,
19 strips they'd mailed to two dead patients. And, when
20 I tried to report it to Medicare, I went through five
21 people, and no one cared. So, even when you try to
22 report these errors and things that are happening out

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1 there, you don't get anywhere.

2 DR. HARPER: We would really like you to
3 report to FDA on that, because we can work with the
4 manufacturers to make sure that those types of
5 complaints are addressed.

6 DR. LOON: Yeah, and the mail order houses
7 are a real problem, I can assure you right now. I try
8 to get my patients to use reputable ones, if I can
9 find some. Or, you know, we got them into what meter
10 to use. But they really -- the mail order houses do
11 not care what they send out.

12 DR. HARPER: We also take trade complaints.
13 You know, complaints about companies. But we really
14 appreciate all this feedback, and Ellen, thank you
15 very much for a wonderful talk.

16 MS. ULLMAN: Thank you.

17 DR. HARPER: So I'll just stay here now, and
18 introduce our next speaker. Dawn Hanson is from St.
19 Agnes Hospital in Baltimore, and she's going to be
20 talking to us about risk mitigation in hospitals.

21 MS. HANSON: Good afternoon, everyone.
22 Let's see if I can get the little thing here to work.

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1 . .thanks for the technical help. This is a rendering
2 of what my hospital is going to look like in about a
3 year and a half. We're building a new, 120-bed
4 patient tower. The problem with that is it makes us
5 budget constrained, so as much as I would like to buy
6 new glucose meters right now, it's not going to
7 happen. Maybe once we're closer to having the tower
8 finished. I'd like to thank the FDA today for holding
9 these meetings. We've had a lot of interesting
10 discussion and I've learned a lot, and I'm going to
11 try to take as much of it back to my hospital as I
12 can. St. Agnes Hospital's been around since 1862.
13 Our current building is about 50 years old. We're
14 about 15 minutes from John's Hopkins and the
15 University of Maryland. Our emergency room sees 86,000
16 visits a year. We trade off with another hospital as
17 being the first busiest ED in the area. We have
18 23,000 admissions a year, about. So we're -- they
19 don't like me to say, We're a community hospital.
20 They like me to say, We're a teaching hospital, which
21 we are. I don't know what's become the problem with
22 saying community anymore, but I guess the trend in

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1 public relations and marketing is to stay away from
2 community. The other thing that the FDA folks wanted
3 me to let you know is that we do use the Sure Step
4 Flex glucose meters. The talk today is going to be on
5 risk mitigation, which we've already been introduced,
6 and we want to talk about what steps we take to
7 control or prevent a hazard from causing harm and to
8 reduce risk to a tolerable or acceptable level. The
9 key to that, for me, is the acceptable level. We've
10 had a lot of discussion over the last two days about
11 20 percent, 15 percent, ten percent. I know 20
12 percent is too much. I don't know if we can get down
13 to 10. To accomplish that, what do we do in the
14 hospital? We have to establish appropriate measures,
15 processes. Part of that is training. Another key is
16 what's practical? What can we afford to do? Part of
17 our risk mitigation framework is we have to follow the
18 Joint Commission standards. We have, in a lot of
19 organizations, point of care testing committees. We
20 have a point of care testing policy that covers all of
21 the expectations that we as a laboratory and nursing
22 have to take care of issues such as glucose meters

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1 that aren't working properly, or new areas that want
2 to put glucose meters in place. This year, we found
3 out that our dialysis center was using a home meter.
4 Our dialysis center is contracted out, so we never
5 really went in there, we didn't know what was going
6 on. But we did a Joint Commission mach-inspection in
7 there and found out that they had three different
8 meters, all different companies. So, we replaced that
9 with a hospital meter and now I have to learn a lot
10 more about the dialysis center. Part of our risk
11 mitigation framework is our computer equipment and the
12 meter software that goes with it, middleware, meters
13 with lockouts, QC and proficiency testing. I'm also
14 going to cover a little bit more with the
15 documentation. Occurrence management, which I don't
16 think anybody really touched on except when one of the
17 docs that talked about his duplicate glucose checks
18 that they originally used for billing. We also use
19 our hospital education department very heavily to help
20 us with a lot of our issues. Joint Commission
21 accreditation standards -- for all of you out there,
22 we've heard a lot of talk about POCT-12 for the CLSI,

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1 we've heard about the ISO 15197 -- did I get the
2 numbers right? We leave and die by the Joint
3 Commission accreditation standards. We're also CAP
4 accredited, but CAP has kind of muddied out the wave
5 testing standards to the point where we almost don't
6 have to be too concerned about them anymore. Our
7 bigger concern is the Joint Commission accreditation
8 standards. They are required to have a Medical
9 Director -- he's supposed to be required -- he's
10 supposed to be responsible. I heard the doctor get up
11 and talk about the different meters that he has used.
12 It'd be -- I'd be really surprised if most the
13 doctors, including my Medical Director, actually knew
14 what brand we used or how it worked. That's not a
15 criticism for him -- he's very busy, he's doing search
16 path and pros and sections, but that's not his area of
17 expertise. For our operator training and competency,
18 one of the new standards for Joint Commission is
19 licensed, independent practitioners. Licensed,
20 independent practitioners are physicians, physician
21 assistants, nursing practitioners, certified nursing
22 anesthetists, and now all of a sudden, we have to

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1 train them for working on any instrument that they
2 perform testing on. And I talked to a lot of people
3 in other hospitals, and they're like, "Well, we don't
4 have doctors that do testing." You'd be surprised
5 what you have out there and who's doing that testing.
6 We recently just trained all of our anesthetists and
7 certified nurse anesthetists. The reason we did that
8 is because we finally got our standards, and we're in
9 our Joint Commission window. So we had to do this big
10 training push, and of course, what we're going to have
11 to do is do that every year. Doctors are particularly
12 hard to get a hold of, and in general, I don't really
13 think they like to be told that they have to be
14 trained on something. And they really don't like it
15 when you tell them that they can't perform testing
16 anymore because they didn't do hands-on competency.
17 Ellen talked a little bit about the package inserts.
18 I totally agree with everything she says about the
19 package inserts. My package insert for LifeScan is
20 like this big and that long. And I read it because I
21 have to, and I read it every time we get a new lot
22 number of glucose meters. I keep looking for things

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1 to change. Sometimes they do. And then I have to deal
2 with getting that information out to a group of people
3 who typically are the nurses. The problem is that the
4 nurses are not the ones that are doing the majority of
5 the testing. It is our patient care technicians and
6 our nursing assistants. The next piece of our
7 framework that we work from is a point of care testing
8 committee or a policy. A committee is great if you
9 can get the people to show up. We tried to establish
10 point of care testing committee -- didn't work out so
11 well for us. What we went to was a hospital-wide
12 policy that gets reviewed every year by me. The Joint
13 Commission requires that all your policies actually
14 get reviewed every three years. We review ours every
15 year. But it is a hospital-wide policy, and it goes
16 through every single responsible group of people and
17 tells exactly what we -- I -- expect them to do. So,
18 I even go to the point -- I list the lab and what
19 we're supposed to do, and then what nursing's supposed
20 to do, what bio-medical education -- or biomedical
21 engineering is supposed to do, hospital education,
22 information systems. We're, as the laboratory in

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1 charge of this testing, and we can't do the whole job
2 by ourselves, but unless you tell people what you need
3 them to do, they're not going to pick-up and offer --
4 everybody is just too busy. Computer equipment -- our
5 vendors tend to give us the minimum requirements
6 necessary. What you see up there is my favorite
7 configuration for my hardware for my LifeScan software
8 to sit on, and right now I have a RAID 1, which is two
9 hard drives, so if one dies the other one picks up.
10 The RAID 3 is better, that's where I'm going next
11 time, and the server operating system. The reason I
12 have this up here is, once you start producing glucose
13 results that get sent to your EMR -- and they're
14 immediately available. We have wireless connection,
15 albeit some manual wireless connection. They want
16 their results and they want them now. So if your hard
17 drive goes down and you only have one, you're out of
18 luck. And there's nothing worse than getting the
19 phone calls from administration because doctors are
20 complaining because they don't have their results and
21 the nurses are having problems doing insulin. So, I
22 recommend anybody to have at least two, if not three,

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1 hard drives on their system that handles their
2 database software, which is what we're going to call
3 here the manufacturer's software. It has a patient
4 result repository. It also does operation
5 certification tracking and QC tracking reports. The
6 patient result repository is especially important to
7 us, especially Joint Commission, because Joint
8 Commission requires us to track the patient, the
9 results -- which we do in the EMR. It also requires
10 us to keep track of what meter that test was performed
11 on, what lot number the strips were, and was the QC
12 performed, and what was the lot number of the QC?
13 This data repository is the only way we can do that,
14 because we can't transmit all the information across
15 to the EMR. The other nice thing it does is it keeps
16 track of our operators. It would be really nice if,
17 in newer software -- and mine's pretty old at this
18 point, we would be able to have the ability to
19 actually send out an e-mail notification to those
20 folks that are coming up on certification. There's
21 probably two to three phone calls a day that we get
22 from somebody saying, "I'm trying to run a glucose and

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1 I can't run a glucose. The meter won't let me run it."
2 Well, that's wonderful, but meantime, we've got a
3 patient they're trying to perform a test on. That's
4 delayed; they have to get somebody else to run the
5 test because we've locked them out. Our operators use
6 a barcode on their I.D. badge and they have to scan
7 that I.D. before the scan the patient I.D. armband
8 before they run a test. So, if they can't do the
9 testing because they haven't done their certification
10 competency, which we require QC every six months --
11 some people require them also to do patient testing --
12 but we have people that actually don't do testing that
13 frequently, so we try to stick with the QC. The QC
14 tracking reports we pull monthly, and this is part of
15 what we do with some of our auditing, and I'm going to
16 talk about that a little bit more when I get down to
17 our occurrence reports. Our software goes from the
18 database software, to middleware, to our lab
19 information system, to the EMR. We pull audit reports,
20 which are patients with duplicate tests, patients with
21 critical results, and patients with results that are
22 zero or greater than 500. Another part of our

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1 framework is our documentation. We have a quality
2 plan, procedures, procedure notes, package inserts,
3 training scripts, training checklists, competency
4 quizzes, and our implementation documents. Oh, she's
5 giving me the five minutes and I've got like a zillion
6 slides to go. The important thing to note here is
7 procedure notes. My procedure for my glucose meter
8 testing system is like 18 pages long because of all
9 the stuff that's required to be in it. Procedure
10 notes are like job aides, quick reference cards. It
11 just has the information on it to get the job done,
12 which leaves out a lot of important information that
13 we just don't have time to get them to read through.
14 We tell them, but they don't retain that much.
15 Occurrence management -- this is where we go back to
16 those reports with duplicate test outliers. Originally
17 we started pulling this report because we charge for
18 our glucoses and it picks up any patient that's had
19 two glucoses within 10 minutes. At 15 minutes, that's
20 where our protocol says if you have a low glucose, you
21 get your insulin, and they repeat it in 15 minutes.
22 So we're looking at anything that's less than 15

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1 minutes -- we set it at 10 -- we get results that are
2 really close, we get the 124, 130. They ran the test,
3 they had a bad feeling, didn't match patient
4 condition, they ran it again, but it was okay. Then we
5 get the 124, 240 -- wasn't okay. What we do -- and
6 this is the same with everything else on the slide --
7 if they don't have a comment with a critical result,
8 or they have a zero, or they have a greater than 500
9 and they didn't send a specimen to the lab,
10 unacceptable QC, or equipment issues, we create a
11 report, it goes to the nursing unit, we have a
12 contact, or it's usually the team leader on the
13 nursing unit, and she's required to follow-up with
14 that person to find out what went wrong, if they knew
15 what went wrong, or why they repeated the test. Or
16 why they didn't put a comment in. Or how they got a
17 zero result. When we first started with the system,
18 we would hold up the duplicate. We would hold the
19 second result. What we came to think about about six
20 months into that is, "Did we hold the right result out
21 of the EMR? Is that the result they treated on?" We
22 had no way of knowing that. So what we started doing

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1 is just releasing all those results -- they're already
2 making that decision on the nursing unit, so why would
3 we hold that result. But when we got the system, that
4 was sort of the recommendation, "Well, you can hold
5 the second result." Yeah, but that's probably the one
6 that they're treating on because that's the second one
7 that they ran. So we no longer do that, however, when
8 we do duplicates, we do credit the patient for the
9 second result -- or the third result, because
10 sometimes two out of three is better. A hospital
11 education -- our hospital education department trains
12 all new employees. My next thing is to get them to
13 train the doctors. They train them on the glucose
14 meter use, hyperglycemia, hypoglycemia policies, and
15 not too much more than that. We train a lot of people
16 every month because staff turns over quite frequently
17 and I can tell you that they don't use the package
18 inserts to train. They also assist with our annual
19 competencies. We do on-line quizzes. We have
20 competency days for instruments because typically they
21 have to have some kind of hands-on training. The
22 meters -- when we get new meters, we validate them

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1 before patient use. We do linearity studies. We do
2 the five levels four times. We run it through the
3 software that the vendor gives us to determine whether
4 the instrument is appropriate to send out, we do QC in
5 duplicate. Typically the meters are good. Probably
6 in the last ten years, I've only had to send one back
7 that didn't meet standards. Infection control -- we
8 have a lot of isolation patients. Over the last two
9 years because of our MRSA surveillance, one of the
10 interesting things that happened to us when we started
11 this whole hand hygiene, put all the gel out there,
12 put the bleach wipes out there. The first week we
13 lost four meters in our intensive care unit because
14 they got them so wet with the bleach wipes that it
15 just seeped right into the meters and they had to get
16 new meters. We had to send them all back. Sorry,
17 LifeScan. We didn't tell them that was what happened,
18 but I'm sure they figured it out. Amy doesn't care.
19 The other problem that we have is just in general, the
20 precautions all over the nursing units. You can go to
21 any one of our nursing units and they have a white
22 film all over them. And hopefully this isn't causing

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1 any other interfering substances -- or interferences
2 with our glucose results. Strips and controls -- we
3 get large quantities every order. We have to do lot
4 to lot comparisons on those and on our QC. Our users,
5 our physicians, physician assistants, nurses, patient
6 care technicians -- I can tell you in my hospital and
7 probably anybody else that has patient care
8 technicians, which are nursing assistants, nursing
9 technicians, they do 80 percent of the testing,
10 including in the intensive care unit. Now in our
11 intensive care unit, if the patient's on insulin drip,
12 insulin I.V. which is what they call it in our
13 hospital -- they don't go as far as tight glyceemic
14 control. The nurses are doing the testing during that
15 instance, but during the rest of the time, it's
16 patient care technicians. Our glucoses, in addition
17 to all the normal places, are used in our labor and
18 delivery suite, on babies that are 15, 20 minutes old.
19 Where are those standards? They're used in the O.R.
20 Not quite -- I'm sure they're testing for glucose, but
21 I don't know under what circumstances. And the one
22 that I love is they do glucoses on patients that are

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1 being recusced. If anybody out there can tell me why
2 they do that, I'd appreciate it. So, I'm just going
3 to flip through these real quick, because these are
4 the things that I wish I had. We talked about
5 standardized meters, smarter software, smarter meters,
6 and I would like -- and we talked about this with
7 Ellen -- I would like when you open the bottle of QC
8 that maybe the cap would change color when it expired,
9 or something similar to that. The other thing that I
10 would like to see are strips that are individually
11 packaged with bar code numbers on them, because then I
12 don't have to worry about how long the bottle was
13 open. And lastly, I think we've talked about this a
14 lot, no result is better than the wrong result. And I
15 learned that a long time ago when I started working in
16 the laboratory, and I would like to not get a result
17 when there is something wrong with that strip. Thank
18 you.

19 DR. HARPER: Thank you, Dawn. That was
20 great. I learned a lot about risk mitigation in the
21 hospitals and a lot of things that I didn't realize.
22 So before I introduce Dr. Klunoff who's going to give

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1 a good summary of the meeting, I'd first like to thank
2 a few of the people who, without them, this meeting
3 wouldn't have happened: Arleen Pinkos, Katy Serrano
4 (ph), Leslie Landry, and all the people that you saw
5 outside. They did a lot of work and worked for months
6 in order to bring this wonderful program to you, so
7 please join me in thanking them. They did a lot of
8 hard work for this. So now I'd like to introduce Dr.
9 David Klunoff. Dr. Klunoff is a Clinical Professor of
10 Medicine at U.C. San Francisco and the Medical Director
11 of the Dorothy L.

12 and James E. Frank Diabetes Research
13 Institute of the Mills Peninsula Health Services in
14 San Mateo, California. Welcome, David.

15 DR. HARPER: Thank you, Courtney. This
16 has been a really interesting meeting for me. I'm
17 going to start by disclosure. I'm a consultant with
18 Bayer, C-8 (ph), Insuline (ph), LifeScan, Madingo
19 (ph), and Rausch. Now, I have an announcement about
20 slides for this meeting. The organization that I'm
21 President of -- a non-profit organization, Diabetes
22 Technology Society -- will post slides of any of the

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1 speakers from this meeting and the mechanism is to get
2 them to Arleen Pinkos, and then she'll get them to
3 Diabetes Technology Society and she'll notify you of
4 the website. Okay. This meeting today has been
5 focused on regulatory standards, and the point I made
6 yesterday was regulatory standards represent what is
7 achievable given the technology and the economic
8 resources that we have. It's a -- there are a lot of
9 things that we like, but the technology or economic
10 resources may not be there yet. Clinical standards
11 are what is desirable, and we've certainly heard some
12 really nice clinical standards today that we would all
13 like to see at some point. What I heard quite a bit
14 of today and yesterday is that there's some idea of
15 having two sets of standards. And there's some
16 precedent for that. For example, if you live in a
17 certain neighborhood, there'll be a speed limit so
18 that you can walk out on your street and not get run
19 over by cars. If you live near a school, there's
20 going to be a slower speed limit. So, we're used to
21 having two speed limits. I mentioned yesterday that
22 if you want to have a building built in California, we

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1 have earthquake standards, but if you want to build a
2 hospital, we have very strict earthquake standards. I
3 could go on with a lot of examples. But my point is
4 that in life, sometimes there is situations where you
5 need accuracy and sometimes you need super-accuracy.
6 So what I'm going to talk about now in the last few
7 minutes of this meeting -- where we go from here, are
8 ten themes which

9 I believe have emerged from this meeting.
10 So the first theme is that we need separate analytical
11 accuracy standards for different populations -- we
12 need accuracy and we need super-accuracy. And we've
13 talked about who these patient populations are: the
14 ICU patients, the Type Is with tight control -- they
15 need super-accuracy. We also need separate clinical
16 accuracy standards for these two types of populations.
17 And a good way to present this information, I think,
18 that both industry, the FDA, and the academic
19 community can agree on, is with a good error grid.
20 And if there's a good error grid which defines the
21 clinical use and how you're going to make decisions
22 with the information, you start with the error grid

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1 and then the FDA can assign what percentage of the
2 data points have to be in the "A" zone. And the
3 reason is, if you're looking at a scatter of points,
4 they'll ideally be on the equality line that goes at a
5 45 degree angle, but they're not always on that line.
6 However, if you try to understand why they're not,
7 because there's problems with interfering substances
8 and problems with bias and individual issues, you
9 start getting into arguments about do the interfering
10 substances count, or do they not count. We heard that
11 yesterday. There are a lot of technical questions
12 that are hard for everybody to deal with when you look
13 at these points that are not right on the line.
14 However, if you take these same points and you assign
15 them an A, a B, a C, a D, or E, whatever, and you
16 specify. They just about all have to be in the "A"
17 zone. We know what "A" zone means -- that's the right
18 zone to be in, and then there's no more arguments. We
19 all understand what that means. So I think in terms
20 of clarity, this is something that we can all get
21 behind, and that's what I'm hearing about using error
22 grid for helping to determine treatments, make

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1 decisions. A third theme is that when we look at
2 data, we need to account for certain types of data
3 which are currently not part of the standards. That
4 includes the five percent outliers. People seem
5 really unhappy knowing that these five percent can be
6 so far off, as well as the no report whatsoever and
7 what does that mean? Technically it doesn't count as
8 an inaccurate reading. That's a relatively easy
9 problem to fix and I think that there is impetus at
10 fixing this. Another theme of this meeting I heard
11 was that we should have some new labeling on the
12 product for both analytical and clinical performance.
13 It's pretty clear how this can be done for analytical
14 performance - - there are different numbers that can
15 be chosen. And for clinical performance, it's also
16 pretty easy because you can take the performance on
17 the error grid and simply say what percentage were in
18 the "A" zone or the "B" zone, or the whatever zones
19 you're even allowed based on the FDA ruling. So
20 people want to see labeling, and I think we're going
21 to see more labeling. Now, a fifth theme deals with
22 interfering substances. We know that these are out

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1 there, but different meters test different substances
2 and test them in different ways. So another theme
3 that I've heard is that we should have specific
4 protocols for how to measure these substances. So if
5 we're going to measure for acetaminophen or whatever
6 we're measuring for -- people measure them in a
7 certain way and when you read that this meter is not
8 affected by acetaminophen, you know what it means.
9 And this can be handled by CLSI which has a committee
10 for interfering substances. This could be added on or
11 they could make their own committee. Also, the sixth
12 theme relates to interfering substances is how they're
13 reported. We do not have a standardized mechanism for
14 reporting. This could also be handled by CLSI by
15 setting up a committee on reporting interfering
16 substances. The seventh theme is that since we want
17 more accuracy -- and we have to realize, and I think
18 many people in this room do realize, that accuracy is
19 going to pay -- you have to pay a price. There's a
20 cost for accuracy. The cost could be dollars. The
21 cost could be having to give up some of the features
22 that we like. For example, we might have to give up

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1 on the rapid time that we like, or the drop size, or
2 having no coding features, or stability reagents, or a
3 small number of steps. Possibly tolerance of various
4 interferences, or not having strips with some systems.
5 We're probably going to have to make a sacrifice in
6 some way -- get used to it. And on the same topic, of
7 what we have to get used to, this might also include
8 some kind of sunset laws to take products off the
9 market under defined conditions. And that would have
10 to be discussed. An eighth theme of this meeting is
11 that we need data to address what are the outcomes and
12 what type of performance will generate those outcomes.
13 We heard a landmark report from Marc Breton at this
14 meeting in which he showed what happens to the
15 performance under defined conditions. He picked
16 certain defini -- he defined certain conditions.
17 Again, I would like to see this group write some more
18 articles. It's very difficult to do empiric studies,
19 but at least due some modeling studies, maybe making
20 different assumptions, and let's get a lot of data out
21 there and look at it. Maybe Marc and Boris will even
22 do another paper. But remember, modeling is very

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1 good. It's as good as the assumptions that are made.
2 We need the data to address this important question.
3 Otherwise when we demand greater accuracy how do we
4 know what we're getting and why we're getting it? We
5 need one more data that would request is that we need
6 to develop some processes to improve the performance
7 of the blood glucose monitoring in addition to greater
8 accuracy. There's a sense here -- we all know it.
9 Yes, the meters should be more accurate. But there's
10 more to getting an accurate reading than the quality
11 of the strip in the monitor. These processes involve
12 various types of education. We've heard all of the
13 things that can go wrong where you don't wash your
14 hands, and when you leave the strips out and there are
15 a million things that can go wrong. And we need some
16 education, because we're not going to get there just
17 by squeezing the strip accuracy. That's part of it,
18 but it's definitely not all of it. The last theme is
19 that we need to define optimal targets for glycemic
20 control in various populations. We spend a half a day
21 today discussing what's an optimal target for
22 hospitalized patients who clearly need tight control,

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1 who clearly need accurate meters, but we have to know
2 what these targets are. So I've mentioned ten things.
3 I'm going to wrap this up with what I would say are
4 five conclusions that I have taken away from this
5 meeting. First is that we want better analytical
6 performance. Second, we want better clinical
7 performance. Third, we want better incorporation of
8 factors which will improve performance of blood
9 glucose monitoring above and beyond the meter and
10 strip, analytic and clinical performance. Fourth, we
11 need better labeling and reporting of interfering
12 substances, and fifth, we need better agreement on
13 glycemic targets for hospitalized patients. And, what
14 I continued to notice today as I did yesterday is
15 there has been a very nice atmosphere between the FDA
16 people, the industry people, the academic people, the
17 patients. I sense that we're all in this together; we
18 all want the same kinds of things. I think if we
19 work together, we're going to get there. And since
20 I'm from San Francisco which is the rock-n-roll
21 capitol, I'm going to end with some words from Mick
22 Jaggar from the Rolling Stones, "You can't always get

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1 what you want, and if you try sometime, you find you
2 get what you need." Thank you.

3 DR. HARPER: Thank you, David. So, now to
4 close the meeting, it's my pleasure to introduce Dr.
5 Alberto Gutierrez, my boss. He's the Director of the
6 Office In Vitro Diagnostic Devices at FDA. So,
7 Alberto.

8 DR. GUTIERREZ: Thanks, Courtney. I want to
9 actually start by thanking Courtney, and actually the
10 Division of Chemistry and Toxicology who are the
11 people who look after glucose meters. And I do want
12 to thank everybody who came to the meeting, and really
13 let you know that this is an extremely important
14 meeting for us. All the discussion that went in the
15 meeting, not only -- I hope that actually you, as I,
16 was somewhat awed by the complexities of how these
17 meters are used and the landscape of what we're
18 dealing with. And in the Division, we make decisions
19 everyday and we put risks and benefits together. And
20 we make decisions when we see an issue, when we're
21 dealing with a recall, when we're looking at new
22 meters and what their performance is, we make

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1 decisions as to how they're going to affect each and
2 every patient out there. So having a good idea of
3 what the landscape is, knowing how the meters are
4 used, knowing how the clini -- what the clinicians are
5 looking for, knowing what problems the users are
6 finding, are of extreme importance to us. So the
7 meeting -- this meeting has been everything we hope
8 for, and you've helped us make a lot of the decisions
9 that we do every day. I want to particular thank
10 Arleen Pinkos, although I was a little worried when
11 Arleen got up and presented herself as being Arleen
12 Pinkos from Baltimore, that she wasn't quite being
13 honest enough. And anybody who knows Arleen actually
14 knows that her heart doesn't bleed purple. She's a
15 rabid Pittsburgh fan. So I'm not sure about this
16 Baltimore stuff. I also want to thank -- there are a
17 couple -- although Courtney mentioned some people that
18 really put in a lot of work like Katie Serrano and
19 Leslie Landry. There were also some people in the
20 outside that were at the tables that really helped put
21 this meeting together and let me just read a couple
22 nam -- a few of their names like Christine Kellerman

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1 (ph), Eddie Selixon (ph), Susan Monoham (ph), Michelle
2 Garza (ph), Peggy Rooney and Renita Hord (ph). And
3 they really, really did a lot of the leg work for this
4 meeting to be put together. And lastly, I want to
5 thank all the speakers and the panelists, and I want
6 to really thank everybody who made comments because
7 everything that was said is really being taken at
8 heart by us. Thank you very much.

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1 CERTIFICATE OF NOTARY PUBLIC

2 I, Natasha Kornilova, the officer before whom the
3 foregoing meeting was taken, do hereby certify that the
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9 action in which this meeting was taken; and further,
10 that I am not a relative or employee of any attorney or
11 counsel employed by the parties hereto, nor financially
12 or otherwise interested in the outcome of this action.

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Natasha Kornilova

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District of Columbia

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19 My commission expires:

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